UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION: 01-CV-12257-PBS Subcategory Docket: 06-CV-11337-PBS
THIS DOCUMENT RELATES TO	Judge Patti B. Saris
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., No. 06-CV-11337-PBS	Magistrate Judge Marianne B. Bowler

UNITED STATES' RESPONSE TO ABBOTT'S STATEMENT OF FACTS IN SUPPORT OF ITS MOTIONS FOR PARTIAL SUMMARY JUDGMENT AND TO EXCLUDE CERTAIN OPINIONS OF PLAINTIFFS' EXPERT

Dated: July 24, 2009

MICHAEL F. HERTZ
DEPUTY ASSISTANT ATTORNEY GENERAL

/s/ Renée Brooker
Joyce R. Branda
Daniel R. Anderson
Renée Brooker
Justin Draycott
Rebecca A. Ford
Gejaa T. Gobena
Elizabeth Strawn
Civil Division
Commercial Litigation Branch
P. O. Box 261
Ben Franklin Station
Washington, D.C. 20044
Phone: (202) 307-1088
Fax: (202) 307-3852

PRELIMINARY STATEMENT

The United States submits this response to Abbott Laboratories, Inc.'s Local Rule 56.1 Statement of Undisputed Material Facts in Support of Its Motion for Partial Summary Judgment. To the extent a statement of fact asserted by Abbott Laboratories, Inc. is undisputed, it is undisputed solely for the purposes of the Abbott Laboratories, Inc. ("Abbott") Motion for Partial Summary Judgment. The United States reserves the right to modify or supplement its responses insofar as the same facts are relied upon by Abbott as support for its Motion in *Limine* to Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D., and to otherwise respond to Abbott's Statement of Facts as necessary. The United States reserves the right to object to the relevance of any and all facts asserted by Abbott.

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I. CASE BACKGROUND

1. The parties to this litigation are the United States of America ("United States" or "Government"), Relator Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care") (collectively, "Plaintiffs") and Defendant Abbott Laboratories, Inc. ("Abbott").

United States' Response: Undisputed.

2. On June 23, 1995, Ven-A-Care filed a *qui tam* Complaint under seal in the United States District Court for the Southern District of Florida. The Complaint was assigned Civil Action No. 95-1354-CIV-GOLD. In its Complaint, Ven-A-Care alleged that a number of pharmaceutical manufacturers, including Abbott, violated the False Claims Act. Ven-A-Care alleged, in part, that Abbott's conduct resulted in fraudulent price inflation on certain products, including dozens of specific infusion and injectable pharmaceutical products. (Ex. A (Original Complaint, Abbott Ex. 414A).)

United States' Response: Undisputed.

3. Ven-A-Care's Original Complaint provided pricing information-specifically, "Relator's Cost"-for a number of Abbott pharmaceutical products, including Abbott's vancomycin, sodium chloride, and dextrose for the years 1993-1995. (*Id.* at 21-27.) These products are three of the four pharmaceutical products currently at issue in this litigation. (Ex. B (The United States's First Amended Complaint, Abbott Ex. 547).)

United States' Response: The United States disputes the materiality of the above statement, but not the facts asserted therein.

4. Tables within Ven-A-Care's Original Complaint compare "Relator's Cost" to "AWP" and "DP" prices published in Red Book and Blue Book for several Abbott pharmaceutical products, including Abbott's vancomycin, sodium chloride, and dextrose. (Ex. A at 21-23, 25-26 (Original Complaint).) For example, the table on page 25 of Ven-A-Care's Original Complaint depicts, for NDC 00074794109 (Dextrose 5% with Sodium Chloride 0.9%), a Blue Book AWP of $11.12 and a Relator's Cost of $1.21 for 1993. (*Id.* at 25.)

United States' Response: The United States disputes the materiality of the above statement, but not the facts asserted therein.

5. At some point prior to the filing of its initial Complaint, Ven-A-Care provided "[a] copy of th[e] Complaint and written disclosure of substantially all material evidence and

information the Relator possesse[d]" to the Government . . . ." (*Id.* at 9.) Plaintiffs have refused to produce the written disclosure statement submitted to the United States, and Magistrate Bowler denied Abbott's motion to compel a copy of the statement. (Ex. C (July 20, 2007 Hrg. Tr. at 27:14-30:13).)

United States' Response: The United States does not dispute that relator provided a written disclosure of evidence to the Government. The United States disputes any implication that the Government's refusal to produce that document to Abbott was improper. The FCA requires that a relator provide a written disclosure of substantially all material evidence and information it possesses. 31 U.S.C. § 3730(b)(2). The material contained therein is attorney work product and covered by a joint prosecution agreement. The United States does not dispute that Magistrate Judge Bowler denied Abbott's motion to compel the production of privileged material. *See* Abbott's Exhibit C (July 20, 2007 Hrg. Tr. At 27-30).

6. Less than three months after Ven-A-Care filed its Complaint under seal, on September 14, 1995, representatives of Ven-A-Care attended a meeting with federal officials from the Department of Justice ("DOJ"), the Health Care Financing Administration ("HCFA"), and the Office of Inspector General ("OIG.") Ven-A-Care produced materials from this meeting, including a participant sign-in sheet, as well as a presentation handout that was discussed with and provided to participants. (Ex. D (Abbott Ex. 545); Ex. E, Z. Bentley Dep. at 329:18-330:04.) The first page of the handout is titled "The False AWP Multi-Billion-Dollar Machine." (Ex. D at VACMDL 86164.) At the bottom of this page, it states that "45% of drug reimbursements create grossly excessive profits for customers of manufacturers who report false AWPs." (*Id.*)

United States' Response: The United States disputes the materiality of the above statement, but not the facts asserted therein.

7. Ven-A-Care's September 14, 1995 presentation also included allegations of the following:

- "Manufacturer's False AWPs v. Providers True Cost" (*Id.* at VACMDL 86165);
- "HCFA Defrauded into Directing DMERCs to Pay Higher Reimbursement Based on False AWPs" (*Id.* at VACMDL 86167);
- "Medicaid Defrauded" (*Id.* at VACMDL 86171);

- "Manufacturer's Incentives to Providers Paid by Medicare/Medicaid/Private Insurers" (*Id.* at VACMDL 86168);

- "Manufacturers Dictate False AWPs to State Medicaid Agencies" (*Id.* at VACMDL 86172);

- "Manufacturers Are Also Wholesalers - Use False AWPs to Promote Drug Sales to Providers" (*Id.* at VACMDL 86166);

- "False AWPs Cause Medicare to Pay More For Generics than for Brands" (*Id.* at VACMDL 86169);

- "Patient-Specific Examples of I.V. Drugs Reimbursed by Medicare" (*Id.* at VACMDL 86174); and

- "Manufacturer's Fraudulent AWPs" (*Id.* at VACMDL 86175).

The presentation also included a comparison of the AWP, Medicaid reimbursement, and "VAC Cost" (Ven-A-Care's cost) for a number of products, including Abbott's vancomycin (*Id.* at VACMDL 86171), as well as a comparison of a Medicare 1994 Allowable and "VAC Cost" for a number of Medicare HCPCS Codes, including the J-Code for 500 mg of vancomycin. (*Id.* at VACMDL 86175.)

United States' Response: The United States disputes the materiality of the above statement, but not the facts asserted therein.

8. On or around October 2, 1996, Ven-A-Care's Zachary Bentley and T. Mark Jones sent a letter to HCFA Administrator Dr. Bruce Vladeck. That letter included the following statements:

> Over a year ago, we traveled to the HCFA in Baltimore and met with various representatives of your agency and made a detailed presentation regarding these excessive reimbursements and their impact on the health delivery system. Unfortunately, for the Medicare and Medicaid programs as well as the American public, to date, no meaningful action has been either proposed or implemented by your agency to deal with these issues. We find this fact not only disconcerting but potentially the source of major embarrassment to both your agency and to the Administration.

(Ex. F at 2 (Excerpts from Abbott Ex. 160).)

United States' Response: The United States disputes the materiality of the above statement, but not the facts asserted therein.

9. Ven-A-Care's October 2, 1996, letter also attached over a thousand pages of information related to drug pricing. Ven-A-Care's attachments included charts it created showing pricing information, including the relator's cost as well as the Florida Medicaid allowable for Abbott's vancomycin, dextrose, sodium chloride, and sterile water. (*Id.* at R2-039475 - R2-039490.) Ven-A-Care's attachments also contained drug pricing catalogs from pharmaceutical wholesalers. The catalogs included drug pricing information for Abbott's vancomycin, dextrose, sodium chloride, and sterile water. (*Id.* at R2-039763, R2-039766, R2-039767, R2-040130, R2-040131, R2-040172.)

United States' Response: The United States disputes the materiality of the above statement, but not the facts asserted therein.

10. On or around January 5, 1998, Ven-A-Care's Zachary Bentley and T. Mark Jones sent a letter to the HHS Inspector General, June Gibbs Brown, the U.S. Attorney General, Janet Reno, and Secretary of the U.S. Department of Health and Human Services, Donna Shalala. The letter included the following statements:

> Be advised that we continue to be appalled and shocked by recent and past public statements made by members of the Executive Branch that the grossly excessive payments by the Medicare and States' Medicaid Programs for the pharmaceuticals at issue are somehow legal waste and are the result of some kind of "loophole." We find the continuance of these types of statements by the highest members of the executive branch particularly disturbing in light of the fact that the Department of Justice has for more than two years continued to make requests for extensions of time causing the specific facts to remain under seal and billions of tax payers monies squandered.

(Ex. G at 4) (Abbott Ex. 56).)

United States' Response: The United States disputes the materiality of the above statement, but not the facts asserted therein.

11. On or around January 22, 1998, Ven-A-Care's Zachary Bentley and T. Mark Jones sent a letter to Congressman Fortney H. ("Pete") Stark. The letter included the following statements:

> As you may be aware, in September 1995 we met with representatives from the OIG and HCFA in Baltimore to discuss and present evidence of the fact that the Medicare and States'

> Medicaid Programs were unwittingly making excessive reimbursements for certain infusion, injectable and inhalation drugs. During that meeting, we were shocked by certain statements made by certain HCFA officials concerning their understanding that the term "AWP" had never been legislatively or administratively defined by the Federal Government.

(Ex. H at 1 (Abbott Ex. 546).)

United States' Response: The United States disputes the materiality of the above statement, but not the facts asserted therein.

12. At his March 19, 2008 deposition, Ven-A-Care's T. Mark Jones was asked about the January 22, 1998 letter sent to Congressman Stark. Mr. Jones provided the following testimony:

> Q. The last sentence on the first page of that letter reads-and this is referring to your meeting in September 1995 with HCFA.
>
> A. Right.
>
> Q. Quote, "During that meeting, we were shocked by certain statements made by certain HCFA officials concerning their understanding that the term AWP had never been legislatively or administratively defined by the Federal Government," close quote. Was that statement made during your September 1995 meeting?
>
> A. I remember it being said that AWP isn't defined. That's how I remember these. I don't remember it being legislatively or administratively defined.
>
> Q. The people who were making that statement, they were the people at HCFA who were responsible for administering the Medicare and Medicaid programs. Correct?
>
> A. To the best of my recollection, I remember it being Sheree Kanner who was the general counsel for HCFA.

(Ex. I, T. Jones Dep. at 551:05-552:5.)

United States' Response: The United States disputes the materiality of the above statement, but not the facts asserted therein.

13. On March 28, 1997, Ven-A-Care filed a Notice of Dismissing and Adding Defendants with the Southern District of Florida relating to its under seal *qui tam*. It stated, among other things, that "Plaintiff hereby voluntarily dismisses, without prejudice, the Defendant[] Abbott Laboratories, [redacted] from the instant action." (Ex. J (ABT008-0671-72).) Other Defendants, whose names were redacted, were added to the action. (*Id.*)

United States' Response: The United States disputes the materiality of the above statement, but not the facts asserted therein.

14. On or around March 28, 1997, Ven-A-Care filed an Amended Complaint with the Southern District of Florida. (Ex. K (ABT 008-0674-75).) Abbott was not named as a Defendant. (Ex. I, T. Jones Dep. at 240:12-18.)

United States' Response: The United States disputes the materiality of the above statement, but not the facts asserted therein.

15. On or around August 12, 1997, Ven-A-Care filed its Second Amended Complaint. Abbott was once again named as a Defendant. (Ex. M (Abbott Ex. 414B).) Ven-A-Care re-alleged claims relating to the 19 NDCs that were first raised in Ven-A-Care's Original Complaint. Ven-A-Care also added claims relating to three new drugs, including NDCs related to Abbott's sterile water. (*Id.*)

United States' Response: The United States disputes the materiality of the above statement, but not the facts asserted therein.

16. On or around December 9, 1999, Ven-A-Care filed its Third Amended Complaint in the Southern District of Florida. (Ex. N (Abbott Ex. 414C).) The Third Amended Complaint did not add or remove any claims as to Abbott. (*Id.*)

United States' Response: The United States disputes the materiality of the above statement, but not the facts asserted therein.

17. On or around December 11, 2002, Ven-A-Care filed its Fourth Amended Complaint. (Ex. O (Abbott Ex. 414D).) Abbott was named as a Defendant. In this Complaint, Ven-A-Care did not add new legal theories of liability against Abbott, but it added new drugs and NDCs, as set forth in an 82-page list designated as "Exhibit 6" to the complaint.

United States' Response: The United States disputes the materiality of the above

statement, but not the facts asserted therein.

18. On March 17, 2006, the United States filed its Notice of Election to Intervene and its Complaint in Intervention against Abbott. The United States intervened "in that part of the action which alleges Medicare and Medicaid fraud with respect to Abbott Laboratories, Inc." with respect to 41 specific NDCs and 11 Specific J-Codes. (Ex. P at 1-2).) The United States's initial Complaint included 44 specific NDCs and 11 specific J-Codes. (Ex. Q (Abbott Ex. 19).) The 44 NDCs and 11 J-Codes relate to four of Abbott's generic pharmaceutical products-vancomycin and solutions of dextrose, sterile water, and sodium chloride. (*Id.*) (Plaintiffs' expert addressed only 5 of those J-Codes in his analysis.)

United States' Response: The United States does not dispute the above statement, except for the conflicting assertions about the number of NDCs listed in the Complaint. The correct number of NDCs identified in the Complaint is 44.

19. On March 17, 2006, Ven-A-Care filed its Motion for Leave to Amend Complaint by Adopting United States' Complaint in Intervention. (Dkt. 4470 at Ex. K). Ven-A-Care sought "leave to amend its complaint as to Abbott only by adopting the United States' Intervention Complaint as Ven-A-Care's complaint against Abbott." (*Id.* at 1.) Ven-A-Care's motion for leave was granted on May 16, 2006. (Dkt. 4470 at Ex. L.)

United States' Response: Undisputed.

20. On June 4, 2007, the United States filed its First Amended Complaint. (Ex. B.) This Complaint sought to add claims related to an additional drug, Acyclovir Sodium. (*Id.* 104-10.) It also added 27 new paragraphs asserting claims related to certain "Home Infusion Pharmacies, Home Infusion Partnerships and Consignment Arrangements" previously operated by Abbott. (*Id.* 104-38.) The First Amended Complaint contained allegations that "Abbott operated its home infusion pharmacies and entered into profit-sharing partnerships with healthcare providers that allowed Abbott to directly profit off Abbott's manipulation of third party reimbursement for its drugs." (*Id.* Opening .)

United States' Response: The United States does not dispute that it filed a First Amended Complaint. The United States disputes any assertion or implication that the allegations relating to the Home Infusion Partnerships constituted new claims. Home Infusion claims which Abbott submitted for the subject drugs were included in the allegations in relator's complaints and the United States' initial complaint. Abbott's Home Infusion is just one of the many providers who benefitted from Abbott's false price reporting scheme. The Amended Complaint merely set out

information learned during early discovery that Abbott itself was among the providers who submitted false or fraudulent claims for the NDCs identified in the complaints.

II. MEDICAID AND MEDICARE DRUG PAYMENT REGULATIONS AND POLICY

A. Medicaid

21. Between 1987 and until the mid-1990s, a publication titled the *Medicaid Pharmacy Bulletin* was published with input from state Medicaid pharmacy officials. (Ex. R, D. Campana Dep. at 187:12-187:13); Ex. S, M. Terrebonne Dep. at 245:12-246:02.) The *Medicaid Pharmacy Bulletin* was designed "to assist the Medicaid pharmacy community in keeping abreast of the latest program management practices and developments in health care policy that affect Medicaid pharmacy." (Ex. T (Abbott Ex. 292).) In its January-February 1987 issue, the *Medicaid Pharmacy Bulletin* included an article titled "Medicaid Reimbursement for the Pharmacy Component of Home I.V. Therapy." (*Id.*) Among other things, that article stated:

> The Establishment of a Fair and Reasonable Pricing Methodology for Home I.V. Products is a Major Concern of Most State Medicaid Programs.
>
> One of the major obstacles to the development of adequate home I.V. pricing methodologies the fact that the dispensing of home I.V. Medications is more complex than the dispensing of other outpatient drugs.
>
> * * *
>
> Providers and Pharmacist Consultants Concur That it is Not Appropriate to Apply the Same Ingredient-Based Pricing Mechanisms to Home I.V. Medications as Those Applied to Other Outpatient Drugs.
>
> For lack of a better alternative, some state Medicaid programs use the same ingredient-based formula they apply to other legend drugs when calculating reimbursement for home I.V. medications. Most pharmacist consultants are not convinced that this process reflects actual provider costs for home I.V. reimbursement. Home I.V. treatments are frequently a combination of multiple drug entities, dispensed in varying doses and administered several times daily. . . . It is, therefore, difficult to estimate, based on single, daily or even weekly administrations, the purchase prices providers are paying with volume and trade discounts. These discounts are generally not revealed in drug pricing publications such as the *Red*

> *Book*, the *Blue Book* and *Medispan*. Consequently, programs are reluctant to increase reimbursement for home I.V. medications, suspecting that reported costs for these substances may already be exaggerated.

(*Id.* at 2-3). The table contained within the article indicated that Oregon based its reimbursement for intravenous prescriptions at "80% of usual and customary charge," that Montana paid the "lower of usual and customary charge or Up to 2 ½ times the cost of ingredients plus a $2.00-$3.75 dispensing fee." (*Id.* at 4.) The chart also indicated that Massachusetts paid a percentage "mark up" on the drug depending on the cost of the drug, whereby lower-priced products received a higher-percentage mark up. (*Id.*) State Medicaid official Cynthia Denemark, Delaware's Pharmacy Consultant, testified that the *Medicaid Pharmacy Bulletins* were "valuable publications." (Ex. U, C. Denemark Dep. at 349:13-351:01.) Former Maryland Medicaid official Joseph Fine also testified that the *Medicaid Pharmacy Bulletins* were a useful source of information containing very reliable information. (Ex. V, J. Fine Dep. at 82:16-83:10.)

United States' Response: The United States does not dispute that Abbott Exhibit T is a publication dated "January-February 1987" titled "Medicaid Pharmacy Bulletin." Further, the United States does not dispute that a state Medicaid pharmacy official testified that a publication titled the Medicaid Pharmacy Bulletin was published "up into the – at least the mid-nineties." (Abbott Ex. R, D. Campana Dep. at 187:12-187:13); that another state Medicaid pharmacy official testified that she recalled obtaining copies of such bulletins (Abbott Ex. S, M. Terrebonne Dep. at 245:12-246:02); that another state Medicaid official testified that they were valuable publications (Abbott Ex. U, C. Denemark Dep. at 349:13-351:01); or that a former state Medicaid official from the State of Maryland testified that the publication was a "useful source of information" that contained very reliable information (Abbott Ex. V, J. Fine Dep. at 82:16-83:10). Abbott has correctly, but selectively, quoted excerpts from the depositions of Messrs. Campana's and Fine's testimony and from Ms. Terrebonne's and Ms. Denemark's testimony. The entirety of those witnesses testimony is the best evidence of its contents. Further responding, the United States notes that although Ms. Denemark testified that the publications were valuable, she also testified that she did not agree with all of the information contained

therein. (Abbott Ex. U, C. Denemark Dep. at 349:13-352:18). The United States does not dispute that Abbott Ex. T includes an article titled, "Medicaid Reimbursement for the Pharmacy Component of Home I.V. Therapy." Abbott has correctly, but selectively, quoted excerpts of that article. The entirety of the article is the best evidence of its content. The United States notes that the article is, and contains, hearsay.

22. For purposes of this litigation, the Government retained the firm of Myers and Stauffer to assist one of its testimony experts, Mark G. Duggan, Ph.D., by collecting information regarding how each of the state Medicaid programs paid providers for dispensing drugs to Medicaid patients. Myers and Stauffer prepared schedules, titled "Medicaid Pharmacy Reimbursement Methodology," for each state. (Ex. AS, Myers and Stauffer Medicaid Pharmacy Reimbursement Methodology Schedules.) The Myers & Stauffer summary for Iowa indicates that "Iowa Medicaid allowed pharmacies to bill for compounded claims using the NDC of one of the active ingredients, adjusting the price to the full compound price online for those claims $30 and under." (*Id.*) Similarly, in New York, the Myers & Stauffer summary indicates that "[r]eimbursement for each compound prescription is restricted to the usual and customary price charged to the general public for the total sum of the ingredients, up to the maximum reimbursable amount ($50.00) . . . ." (*Id.*)

United States' Response: The United States does not dispute that it retained the firm of Myers and Stauffer to provide consulting services in connection with the above-captioned case, or that, among other things, Myers and Stauffer provided support to Plaintiffs' damages expert, Mark G. Duggan, Ph.D. Nor does the United States dispute that Myers and Stauffer researched and summarized drug reimbursement methodologies used by state Medicaid agencies and prepared schedules titled "Medicaid Pharmacy Reimbursement Methodology" for 48 states[1] and the District of Columbia (hereinafter referred to as a "State"), including the States of Iowa and New York. (Henderson Decl. at ¶ 24). Further, the United States does not dispute that the Medicaid Pharmacy Reimbursement Methodology for the State of Iowa indicates that, prior to October 1, 2003, "Iowa Medicaid allowed pharmacies to bill for compounded claims using the

[1] The United States is not pursuing claims with respect to damages to Arizona or Ohio's Medicaid programs. (*Id.*).

NDC of one of the active ingredients, adjusting the price to the full compound price online for those claims $30 and under." (Abbott Ex. AS, Myers and Stauffer Medicaid Pharmacy Reimbursement Methodology Schedules). Further responding, the same entry also notes that claims that exceeded $30 had to be billed on the Universal Claim Form on an ingredient by ingredient basis. (*Id.*). The United States does not dispute that the Medicaid Pharmacy Reimbursement Methodology prepared by Myers and Stauffer related to New York indicates that beginning in 1998, "[r]eimbursement for each compound prescription is restricted to the usual and customary price charged to the general public for the total sum of the ingredients, up to the maximum reimbursable amount ($50.00) . . . ." (*Id.*). Further responding, the summary also notes that "starting around December 1, 2000 there appeared to be an option to bill compounds using the NDCs of the individual ingredients. If this option is used the claim for the compound can not be distinguished from a claim for a non-compounded prescription. Each ingredient payable would be reimbursed at the current dispensing rate plus a dispensing fee less a co-pay. With this option, there is no compound indicator on these claims, there is no compounding fee with these claims and they look like other non-compound claims." (*Id.*).

23. In 1999, under contract from the Louisiana Department of Health and Hospitals, Myers and Stauffer prepared a report analyzing the pharmacy dispensing costs and drug acquisition costs for providers serving Louisiana Medicaid beneficiaries. Myers and Stauffer found that "the costs to dispense I.V. prescriptions are not representative of the costs incurred by a general pharmacy" because "the activities and costs involved in filling I.V. prescriptions are significantly different." (Ex. W at 20-21 (Excerpts of Abbott Ex. 1051).) Myers and Stauffer concluded that "[a]lthough typical dispensing fees reimburse less than the dispensing costs of I.V. pharmacies, they are generally able to break even based on the margin allowed on the ingredient cost reimbursement." (*Id.* at 21 n.8.)

United States' Response: The United States does not dispute that Abbott Ex. W is an excerpt from a September 1999 report titled "A Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the State of Louisiana," prepared by Myers and Stauffer LC for the Louisiana

Department of Health and Hospitals. Abbott has correctly, but selectively, quoted excerpts of that report. The entirety of the report is the best evidence of its content. Further responding, with respect to the excerpts of the report relating to pharmacies dispensing I.V. prescriptions cited by Abbott, those findings were based upon a limited sample of 28 pharmacies.

24. In 2001, under contract from the Kentucky Department for Medicaid Services, Myers and Stauffer prepared a report on the cost of dispensing prescription medications to Kentucky Medicaid recipients. The report was titled "A Survey of Dispensing costs of Pharmaceuticals in the Commonwealth of Kentucky." In its analysis of pharmacy dispensing costs, Myers and Stauffer found that "pharmacies that dispense I.V. prescriptions as a significant part of their business can have dispensing costs far in excess of those found in a traditional pharmacy." (Ex. X at 20 (Excerpts of Abbott Hansen Ex. 6).) Pharmacists interviewed by Myers and Stauffer indicated that "the activities and costs involved in filling I.V. prescriptions are significantly different from the costs incurred by the typical retail (or long term care) pharmacy." (*Id.* at 19.) In 2001, the Kentucky Department for Medicaid Services reimbursed providers who administered intravenous prescriptions based on a fixed dispensing fee plus ingredient reimbursement formula. Myers and Stuffer concluded that "[a]lthough dispensing costs at intravenous pharmacies is well in excess of the current dispensing fee, this reimbursement methodology has been accepted by these pharmacies because the margin on ingredient reimbursement has allowed pharmacies to offset any shortfall from the dispensing fee." (*Id.* at 46.)

United States' Response: The United States does not dispute that Abbott Exhibit X is an excerpt from a November 2001 report titled "A Survey of Dispensing costs of Pharmaceuticals in the Commonwealth of Kentucky", prepared by Myers and Stauffer for the Kentucky Department for Medicaid Services. Abbott has correctly, but selectively, quoted excerpts of that report, and some of the pages to which Abbott cites are not included in Exhibit X. The entirety of the report is the best evidence of its content. Further responding, with respect to the excerpts of the report cited by Abbott, Myers and Stauffer's findings were based upon a limited sample of 11 pharmacies who responded to the survey; Myers and Stauffer indicated that, for a number of reasons, it was difficult for it to determine with any degree of stability an average dispensing cost for I.V. pharmacies; "Myers and Stauffer has typically seen extreme variation in the dispensing

cost calculated for pharmacies that provide intravenous prescription services"; and that the "average (mean) dispensing cost . . . is highly unstable." (Abbott Ex. X at 45).

25. In 2002, under contract from the California Department of Health Services, Myers and Stauffer prepared a report titled "Study of Medi-Cal Pharmacy Reimbursement." (Ex. Y at (Excerpts of Abbott Schondelmeyer Ex. 4).) The report stated: "In every dispensing cost survey performed by Myers and Stauffer in which data on the provision of intravenous services was collected, the provision of this service has been associated with higher dispensing costs. (*Id.* at 59.) Myers and Stauffer concluded that the average intravenous prescription "would yield a margin on ingredients of approximately $42." (*Id.* at 60.) The report stated: "This margin typically allows for adequate reimbursement of the pharmacy's dispensing cost. So long as the ingredient reimbursement rate remains at AWP minus 5% or any other relatively 'high' level, the need for the Department to set a separate dispensing fee for intravenous drugs is somewhat mitigated by the margins realized on ingredient reimbursement." (*Id.*)

United States' Response: The United States does not dispute that Abbott Exhibit Y is an excerpt from a June 2002 report titled "Study of Medi-Cal Pharmacy Reimbursement", prepared by Myers and Stauffer LC for the California Department of Health Services. Abbott has correctly, but selectively, quoted excerpts of that report. The entirety of the report is the best evidence of its content. Further responding, with respect to the excerpts of the report cited by Abbott, Myers and Stauffer's findings were based upon a limited sample of 34 pharmacies who responded to the survey; Myers and Stauffer indicated that, for a number of reasons, it was difficult for it to determine with any degree of stability an average dispensing cost for I.V. pharmacies in the survey; "Myers and Stauffer has typically seen extreme variation in the dispensing cost calculated for pharmacies that provide intravenous prescription services"; and that the "average (mean) dispensing cost . . . is highly unstable." (Abbott Ex. Y at 58-59).

26. Myers and Stauffer published other reports for state Medicaid programs that detailed the increased dispensing costs associated with the provision of home infusion and I.V. solutions. These include:

- Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the Commonwealth of Kentucky, October 2003 (Ex. Z (Excerpts of Abbott Ex. 1110));

- Survey of Dispensing Costs in the State of Kansas, September 1999 (Ex. AA) (Excerpts Attached);
- Survey of Dispensing Costs in the State of Arkansas, June 2001. (Ex. AB) (Excerpts Attached);
- Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the State of California, December 2007 (Ex. AC (Excerpts of Abbott Schondelmeyer Ex. 3));
- Analysis of Pharmacy Dispensing Fees for the Indiana Medicaid Program, August 2005 at 24-25. (Ex. AD (Excerpts of Ex. Abbott Shirley-7)); and
- Determining the Cost of Dispensing Pharmaceutical Prescriptions for the Texas Vendor Drug Program, August 2002 (Ex. AE (Excerpts of Abbott Ex. 21).)

United States' Response: The United States does not dispute that Myers and Stauffer published other reports for state Medicaid programs, including the reports found at Abbott Exhibits Z, AA, AB, AC, AD and AE. The United States does not dispute that, for the limited number of home infusion and I.V. pharmacies that responded to the Myers and Stauffer surveys described in Abbott Exhibits Z, AA, AB, AC, AD and AE (Kentucky-15, Kansas-7, Arkansas-6, California-32, Indiana-11, and Texas-43), Myers and Stauffer reported increased dispensing costs associated with the provision of home infusion and I.V. solutions. The United States, however, disputes any further characterization of the reports by Abbott, and states that the entirety of the reports is the best evidence of their content.

27. State officials have testified that they permitted or were aware that their drug reimbursement systems paid a margin on ingredient cost. For example:

(a) Cynthia Denemark, Pharmacy Consultant for Delaware Medicaid, testified:

Q. The question was whether dispensing fees were adequate to cover dispensing costs or whether there was knowledge among Medicaid providers whether dispensing fees were adequate, sufficient to cover dispensing costs?

MS. HEALY: Objection.

THE WITNESS: My recollection is that Medicaid officials realized that current dispensing fees of the time were not sufficient to cover the dispensing function, the cost associated with the dispensing function.

* * *

BY MR. CYR:

Q. . . . Was that seen as a problem in terms of ensuring adequate participation in the Medicaid program by providers?

MS. HEALY SMITH: Objection.

THE WITNESS: No.

BY MR. CYR:

Q. And was that because the-there was a margin in the ingredient portion cost of the reimbursement payment?

A. Yes.

Q. Have you ever heard of the term cross subsidization in connection with the ingredient portion as a way to make up for inadequate dispensing fees?

A. I'm not sure that I've heard that specific term but I would agree that it probably applies to the situation.

(Ex. AF, C. Denemark Dep. at 180:11-181:22.)

(b) Susan McCann, Missouri Pharmacist Consultant, testified:

Q. . . . But is it your belief and your understanding as the pharmacist working at Missouri Medicaid that Missouri Medicaid knew it was paying a higher ingredient cost reimbursement than acquisition cost in order to compensate for a dispensing fee that was lower than what it otherwise thought it should have been?

Ms. Adams. Object to the form of the question. Misstates her earlier testimony. Calls for speculation.

A. That was my understanding.

(Ex. AG, S. McCann Dep. at 479:6-16.)

(c) Cody Wiberg, former Minnesota Medicaid Pharmacy Director, testified:

A. . . . We know AWP, "ain't what's paid." But if we move towards more transparency and we get closer to reimbursing on the ingredient side at what providers actually pay, then we have to look at the dispensing fee side in the case of pharmacies, because we've always kept that below what we think the true cost of dispensing is to make up for the fact that there is some money being made on the ingredient side. So to the extent, again, that you start paying people a dispensing fee or a total reimbursement that does not even get back the cost of the drugs, plus the cost of labor and the computer systems and the lights and all that, you could have providers stop-you know, start dropping out of Medicaid. And then this creates an access issue for very poor people.

(Ex. AH, C. Wiberg Dep. 172:3-18.)

(d) M.J. Terrebonne, Louisiana Pharmacy Director, testified:

Q. If you look to the footnote 8 on page 21 of the Myers and Stauffer report–

A. Right.

Q. –that states–Would you read that into the record?

A. "Although typical dispensing fees reimburse less than the dispensing cost of I.V. pharmacies, they are generally able to break even based on the margin allowed on ingredient cost reimbursement."

Q. And do you have an understanding of–of what that's saying?

A. I believe what he's saying is that there's a margin on the ingredient side, so that's how they're generally able to dispense.

Q. And this is something that–that you would have read back in 1999; correct?

MR. FAUCI: Objection to form.

THE WITNESS: Probably.

BY MR. TORBORG:

Q. Okay. And if you disagreed with that footnote, would you have told Myers and Stauffer that?

A. Well, they were the surveyors, so they had the information. We were relying on–

Q. Well, was it your understanding, Miss Terrebonne, that because of the higher cost to dispense home I.V. drugs and the fact that Louisiana was only paying a $5.77 dispensing fee for those drugs, that the margin being earned on the ingredient cost was covering that cost to dispense?

MR. FAUCI: Objection to form.

THE WITNESS: Based upon the survey results, yes.

(Ex. S, M. Terrebonne Dep. at 91:11-93:1.)

(e) Benny Ridout, former North Carolina Medicaid Director, testified:

Q. You mentioned that it was common knowledge that Vancomycin had a spread, do I have that correct?

MS. HAYES: Objection to form.

A. Yes.

Q. When was it common knowledge that Vancomycin had a spread?

A. I don't remember the year, just like it was this, but I just remember that drug was one of the antibiotics.

Q. Do you recall whether it was similarly common knowledge that infusion products had spreads?

MS. YAVELBERG: Objection, form.

MS. HAYES: Objection, form.

A. We had no idea what the specialty pharmacists were paying for that drug, what kind of deals they struck with the manufacturers, but it was of their opinion of us that there was some kind of spread in there because of what they were able to do that a regular pharmacist couldn't do at AWP. You see, we still paid at AWP.

Q. What do you mean what they could do that other pharmacists couldn't?

A. Infusion drugs is a whole lot more than just putting a pill in bottle. You got to prepare. In fact, the pharmacists wanted a special fee to do this under-the-hood preparation, you know, also injection takes longer, you got to have syringe and all the stuff to do

that. Of course they were shipping that on top of the cost to ship the product. If you add up all that extra cost in a regular pharmacy or regular pills, you know, you think well, how in the world can they afford to do this and accept that same price?

Q. What was your conclusion?

A. That somehow they were getting some kind of special deal back or discount from the manufacturers to be able to do it or something. That was just my own personal feeling. How did they do it?

(Ex. AI, B. Ridout Dep. 62:6-64:3.)

Q. You mentioned earlier your belief that given the amount of services that some of these specialty pharmacies were providing, that you were led to believe that they were buying drugs at deeper discounts. Do you recall that testimony?

MS. YAVELBERG: Objection, form.

MS. HAYES: Objection, form.

MS. YAVELBERG: I don't believe that was his testimony.

A. I just said that I don't see how they could do it for that. I have no idea what they were buying it for, what was going on.

Q. Leaving aside the specifics of what they were paying for it, you had an understanding, am I correct, that they were making profit on the drug side?

MS. YAVELBERG: Objection, form.

A. I had to assume that if I was taking ten percent off of that price, and they were providing all this service, that somehow they had to be getting some kind of help from somewhere. I mean, I couldn't see how they can do it with me taking ten percent off of the drug cost and then them providing those extra services and billed for that. That was my opinion.

(*Id.* at 72:13-73:16.)

(f) H. Leo Sullivan, former Director of Pharmacy Services for TennCare, testified:

A. . . . So getting back to, to the MAC issue, some, sometimes for certain products in this arena, you would take that into account for the MAC. For example, I might say, I'm not paying for the tape that you use to hold the IV needle into place. I'm not paying for the IV needle or the tube set. I'm not going to-I don't want bills for that. I know you've got to do it to administer this drug. So we're going to add on the cost of this drug X, because I know this, this and this always goes with it, and I know there is a fixed cost for that, but I don't want five bills. I want 10 different places. Bill me for the drug. And I'll make sure that the-whatever the MAC is incorporates all your other costs. And you have to talk with providers and know what that is. I mean, you know.

Q. So, in short, you would use the payment for the drug itself to cross-subsidize other things that might need to be paid to fairly–

A. And that would include compounding.

Q. And it may include nursing services that were not included, things of that nature?

A. (Nodding yes.)

Q. Did anyone in the federal government ever tell you that you were not allowed to do that?

A. No.

(Ex. AJ, H. Sullivan at 153:20-155:04.)

United States' Response: The United States does not dispute that Cynthia Denemark, Susan McCann, Cody Wiberg, M.J. Terrebonne, Benny Ridout and H. Leo Sullivan testified as set forth above. Abbott has correctly, but selectively, quoted excerpts from the testimony of those witnesses. The entirety of the testimony referenced is the best evidence of its contents. Further responding, Medicaid officials, including some of the same Medicaid officials Abbott quotes above, testified that:

(a) Their State's dispensing fees were adequate and/or that Medicaid paid higher dispensing fees than other commercial payors. (*See, e.g.*, Lavine Decl. at Ex. USAbt-A, C. Denemark Dep. at 179:17-180:8 (Delaware); Ex. USAbt-C, S.

Bridges Dep. at 66:19-67:9 (Arkansas); Ex. USAbt-D, A. Chapman Dep. at 145:1-146:21 (Colorado); Ex. USAbt- E, J. Dubberly Dep. at 364 (Georgia); Ex. USAbt-F, J. Parker Dep. at 165-165, 341-342 (Illinois); Ex. USAbt-G, J. Fine Dep. at 141-142, 307 (Maryland); Ex. USAbt-H, G. Cheloha Dep. at 364:8-367:13 (Nebraska); Ex. USAbt-I, R. Stevens Dep. at 305-306 (New Mexico); Ex. USAbt-J, A. Rugg Dep. at 253-255 and 261-262 (Vermont)).

(b.) Their State did not have a policy or practice of permitting overpayments on acquisition cost to offset purportedly inadequate dispensing fees. (*See, e.g.*, Lavine Decl. at Ex. USAbt- K, D. Campana Dep. of Aug. 21, 2008 at 269:11-273:21, 312-319 (Alaska); Ex. USAbt- C, S. Bridges Dep. at 68:6-68:15 (Arkansas); Ex. USAbt-L, K. Gorospe Dep. of Dec. 3, 2008 at 298, and Ex. USAbt-M, D Hillblom Dep. at 93-94 (California); Ex. USAbt-E, J. Dubberly at 76-77, 355-358 and 361-363 (Georgia); Ex. USAbt-F, J. Parker Dep. at 61 (Illinois); Ex. USAbt-N, S. McCann Dep. at 607:9-607:17 (Missouri); Ex. USAbt-H, G. Cheloha Dep. at 370-372 (Nebraska); Ex. USAbt-O, L. Farrand Dep. at 251-252, and Ex. USAbt-R, P. Clifford Dep. at 212-213 (New Hampshire); Ex. USAbt-Q, E. Vaccaro Dep. at 97-99 (New Jersey); Ex. USAbt-I, R. Stevens Dep. at 316-3:18 (New Mexico); Ex. USAbt-R, L. Weeks Dep. at 77-78 (North Carolina); Ex. USAbt-J, A. Rugg Dep. at 235-237 (Vermont); Ex. USAbt-S, B. Tomlinson Dep. at 78-79 (Virginia); Ex. USAbt-T, M. Davis Dep. at 63:5-66:21 and Ex. USAbt-U, A. Hautea-Wimpee Dep. at 127:22-133:12 (Washington)).

©.) Manufacturers never suggested to Medicaid officials that the manufacturers were reporting, or requested permission to report, inflated AWPs to make up for

purportedly inadequate dispensing fees paid by the State, and State Medicaid officials never told manufacturers that they understood or approved of manufacturers reporting inflated AWPs. (*See e.g.*, Lavine Decl. at Ex. USAbt-L, K. Gorospe Dep. of Dec. 3, 2008 at 293-295 (California); Ex. USAbt-B, C. Denemark Dep. at 485:1-486:13 (Delaware); Ex. USAbt-E, J. Dubberly Dep. at 76-77 and 355-358 (Georgia); Ex. USAbt-I, R. Stevens Dep. at 322-323 (New Mexico); Ex. USAbt-T, M. Davis Dep. at 63:12-66:21, 68:8-70:12, and Ex. USAbt-U, A. Hautea-Wimpee Dep. at 141:17-144:10, 147:4-148:12, 155:18-161:13 (Washington)).

Further responding, State Medicaid programs were required to make dispensing fee determinations separate and distinct from ingredient cost determinations for each drug. (*See, e.g.*, Lavine Decl. at Ex.59, State Medicaid Agency Regional Bulletin, No. 94-25, dated September 6, 1994 (Ex. U.S.- AB, HHC006-428 - HHC006-429) stating: "[W]e would also clarify our policy that a dispensing fee determination must be separate and distinct from the EAC determination and unrelated to the cost of the drug product."

28. State officials provided the following testimony regarding the source of pricing information they used to establish MACs:

(a) Tennessee's H. Leo Sullivan testified:

Q. Now where would you get the information that you would use in the MAC program regarding what pharmacists were– pharmacies were actually paying for drugs?

A. My, my system was, was not very sophisticated or very scientific, but nonetheless believe it to have been very effective. What I did was, I knew I had a contact within the largest generic distributor in our area, and one of the most-one of the more popular. Again during this time that I, that I was setting MAC prices, rather than MCOs or PBMs, the, the best deal on generic weren't coming from, from big wholesalers. They were coming

> from generic distributors. So I had contacts within this one particular company who would tell me, who would first of all keep me apprized any time they, they were able to distribute new generic drugs, also give me information if, if there was some problem with an existing generic drug's availability, and also tell me and give– send me catalogs that they sent to the pharmacists and then tell me additionally what am I looking at for this drug X, Y, Z, what does a hundred of them cost a pharmacy? I didn't look at Red Book or Blue Book or First Data; I called the people that sell it. . . .

(Ex. AJ, H. Sullivan Dep. at 106:18-107:22.)

> Q. But you used a MAC program to reimburse generic drugs; is that right?
>
> A. Yeah. Now I thought you were talking about brand name in your original question. I keep the two totally separate. I have never reimbursed anybody for generic based on AWP.
>
> Q. So would it be fair to say that you believed you had another choice to set reimbursement rates for generic drugs?
>
> A. Oh, yes.
>
> Q. Apart from the compendia.
>
> A. Yes. Yes. I'm sorry.

(*Id.* at 115:20-116:10.)

> (b) Ohio's Robert Reid testified:
>
> Q. So the prices that you used to set the MAC amount, those were based on actual prices that you got from pharmacies; correct?
>
> A. Right.
>
> Q. They are not based on–
>
> A. Well, partly, yeah.
>
> Q. What else were they based on?
>
> A. Well, we would take the First DataBank price into consideration, although rarely use it on the grid, unless it was reasonable, comparable.

Q. So if the First DataBank price was not comparable to the other prices, you wouldn't use it?

A. No. I would consider it to be an outlier.

Q. If it was an outlier, it wouldn't even go into the 65th percentile calculation?

MS. GEOPPINGER: Object to the form of the question.

Q. You can answer.

A. Yes.

Q. And you did all this by yourself?

A. I did it all by myself up until 2001.

(Ex. AK, R. Reid Dep. at 160:19-161:20.)

(c) Maryland's Joseph Fine testified:

Q. So you got pricing information from either wholesalers or a pharmacist who cooperated with the department in giving–

A. But it was from wholesalers. It was always wholesale prices. It was the wholesaler file. But since they wouldn't let us use it directly we had to go through them to get the files.

Q. When you say wholesale file–

A. Meaning the price list. The drug price list.

Q. We're not talking about the compendia here?

A. No. Maryland did not use compendia, meaning we did not use First Databank and/or Medi-Span to set our IDC. We were determined to set our state MAC or IDC based on what local–what our pharmacists could get the drug for if they were working and buying the product from a wholesaler that was selling in Maryland.

Q. And this process of going to get wholesale price lists from either a wholesaler or a pharmacist, some of that was just part of your job, right?

A. Correct.

Q. Something you felt you needed to do to get fair pricing for drugs?

MS. YAVELBERG: Objection, form.

A. Well, the feel–it's not my feeling. It's what Maryland decided to do to get fair pricing to their pharmacists who fill prescriptions for Maryland medical assistance recipients.

Q. And you received cooperation from the pharmacy providers in this effort?

MS. YAVELBERG: Objection, form.

A. Yes. Yes. The pharmacy providers worked with us.

(Ex. V, J. Fine Dep. at 203:8-204:19.)

(d) Nebraska Medicaid's 30(b)(6) witness, Gary Cheloha, provided the following testimony regarding how Nebraska established MACs:

Q. Once you determined that there's a particular drug that you'd like to set a maximum allowable cost for, how do you go about setting that actual price?

A. Ask for a recommendation from Pace Alliance. We'll also call pharmacies to determine the range of costs or range of recommended–recommendations for SMAC pricing.

Q. Okay. So if you find out from Mr. Woods at Pace that, for a particular prescription drug, that he can purchase it for, say, 50 cents for that particular dosage, I mean, do you use that figure? Or is there a calculation involved in taking that number and turning it into a MAC?

A. Into an actual SMAC price?

Q. Uh-huh.

A. There is no set formula, and he doesn't provide us-I think he has–I believe he has confidentiality agreements for the actual price that the Alliance members can purchase the drug for. So–and we rely mostly on the Pace recommendations.

Q. So he'll give you kind of a range, and you'll–

A. He'll generally quote a specific price. He'll say 8 cents, 10 cents. I recommend this for the SMAC price on it.

Q. And do you know–you said that there's some confidentiality provisions as far as what they're actually paying. Do you know if he bills in some percentage or

a few cents here or there to make sure that other people can get that or to account for profit or anything like that?

A. All I would know for sure is that it's more than the contract price, but I don't know whether he uses a specific formula or how he specifically determines that. He–from time to time, on a very limited basis, he and I have discussed-how will I say it-the price that the pharmacies pay. And then I would–when I was doing it, I made a determination of where to set the MAC price, at something above that.

Q. And did you have a formula, or you were just–it was a case-by-case basis for–

A. Generally, a case–it was a case-by-case basis. I did not have a set formula.

Q. And I'm assuming that the–you said that Pace is a purchasing organization that has pharmacies in Nebraska, and those pharmacies are participants in the Medicaid program?

A. Yes.

(Ex. AM, G. Cheloha Dep. at 130:10-132:17.)

United States' Response: The United States does not dispute that H. Leo Sullivan, Robert Reid, Joseph Fine or Gary Cheloha testified as set forth above. Abbott has correctly, but selectively, quoted excerpts from the testimony of those witnesses. The entirety of the testimony referenced is the best evidence of its contents. Further responding, Messrs. Reid's and Sullivan's testimony was given in their individual capacities; they were not testifying on behalf of their respective States of Ohio and Tennessee.

29. Jerry Wells, the Pharmacy Program Manager at Florida Medicaid, provided the following testimony regarding the factors that went into Florida's MAC pricing levels:

Q. When you established those MACs, were you trying to set the MAC at exactly the acquisition cost of providers or at some point above or below the acquisition cost for providers?

A. We would not have tried to set acquisition or the reimbursement level below acquisition cost. We would try to set the reimbursement level at a point where 95 percent of the providers could purchase the drug at or below that price.

(Ex. AL, J. Wells Dep. at 229:22-230:10.)

United States' Response: The United States does not dispute that Mr. Wells testified as set forth above. Abbott has correctly, but selectively, quoted excerpts from Mr. Wells' testimony. The entirety of his testimony is the best evidence of its contents. Further responding, Mr. Wells' testimony was given in his individual capacity; he was not testifying on behalf of the State of Florida.

30. Tennessee's H. Leo Sullivan provided the following testimony regarding the factors that went into Tennessee's MAC pricing levels:

> Q. And do you know in Tennessee, either before TennCare or after TennCare was paying a compounding fee for IV? Do you know if that was something that was being paid?
>
> A. Ah, no. But there's, there's ways to pay it without, without having a separate-you know, I noticed on here that one form is for payment, one form is for reimbursement of supplies, one form is for–you know, they're, they're making a variety to submit multiple forms. And I wouldn't–I can't tell you a specific product or specific time period, but one of my strategies was in issues like this, where compounding was involved, I didn't want to go down the road, at least in the early Nineties, of getting into paying for compounded prescriptions, because that can–that could range from a sterile product all the way down to an ointment, okay? And, and our claims reimbursement system hadn't evolved to the current NCPDP sophistication of today. So it was very hard to put in a, a set compounding fee for what, what products? One may take a minute to make, one may take an hour and a half. So getting back to, to the MAC issue, some, sometimes for certain products in this arena, you would take that into account for the MAC. For example, I might say, I'm not paying for the tape that you use to hold the IV needle into place. I'm not paying for the IV needle or the tube set. I'm not going to–I don't want bills for that. I know you've got to do it to administer this drug. So we're going to add on the cost of this drug X, because I know this, this and this always goes with it, and I know there is a fixed cost for that, but I don't want five bills. I want 10 different places. Bill me for the drug. And I'll make sure that the–whatever the MAC is incorporates all your other costs. And you have to talk with providers and know what that is. I mean, you know.
>
> Q. So, in short, you would use the payment for the drug itself to cross-subsidize other things that might need to be paid to fairly–
>
> A. And that would include compounding.

Q. And it may include nursing services that were not included, things of that nature?

A. (Nodding yes.)

(Ex. AJ, H. Sullivan Dep. at 152:16-154:22

United States' Response: The United States does not dispute that Mr. Sullivan testified as set forth above. Abbott has correctly, but selectively, quoted excerpts from Mr. Sullivan's testimony. The entirety of his testimony is the best evidence of its contents. Further responding, Mr. Sullivan's testimony was given in his individual capacity; he was not testifying on behalf of the State of Tennessee.

31. Washington's Ayuni Hautea-Wimpee provided the following testimony regarding the factors that went into Washington's MAC pricing levels:

Q. And when setting AMAC, you would look at pricing available to wholesalers?

A. From wholesalers, yes.

Q. Excuse me, from wholesalers?

A. Um hum.

Q. In Washington State?

A. Yes.

Q. Okay. And you would look at an array of those prices and determine at what price pharmacists could actually obtain the product for?

A. Correct.

Q. And you mentioned that one concern was access; is that correct?

A. Yes.

(Ex. FQ, A. Wimpee Dep. at 108:4-18.)

United States' Response: The United States does not dispute that Ms. Hautea-Wimpee testified as set forth above. Abbott has correctly, but selectively, quoted excerpts from Ms. Hautea-Wimpee's testimony. The entirety of her testimony is the best evidence of its contents.

32. Minnesota's Cody Wiberg provided the following testimony regarding the factors that went into Minnesota's MAC pricing levels:

> Q. Mr. Wiberg, I'd like to -- or Doctor Wiberg. I apologize for that. I've been calling you "Mr." all day. I would like to take you back to the Zantac example you gave earlier.
>
> A. Yes.
>
> Q. I think you said the AWP was 90 cents.
>
> A. Around there, yeah.
>
> Q. The MAC was about 25 cents, and the AAC was about 6 cents, right?
> A. Well, the -- the actual acquisition costs for the store I worked as was -- was -- was around 6 cents, as I recall.
>
> Q. So 25 cents is what the State Medicaid Program chose to pay for that 6 cent pill, right?
>
> A. That's correct.
>
> Q. Isn't that about a 400 percent spread, between 6 and 25?
>
> A. Well, again, you can't -- people don't spend percentages. They spend dollars. And what the goal was -- and I don't have a calculator handy, but if you do the math, typically we're talking about 60 tablets. In a typical prescription. So, you know, the actual math is -- is they're not getting huge amounts of actual dollars. And at some point, I think we reduced the MAC. Part of -- well, let me just say that when I came on board at the Minnesota Department of Human Services, there was one pharmacist working. We used the pharmacy program manager, he was working there by himself. He had three rebate analysts. There had been more pharmacists working for the Department earlier, but they worked in different divisions. In fact, there wasn't a pharmacy program a year-and-a-half before I started. There was no coherent Pharmacy Management Policy. And as a result of that, we made -- after I took over, we ended up making massive changes. It went from, in my opinion, being a program that was not very effectively managed, to being one that is very aggressively managed now.
>
> So -- and the other issue that we had - I mentioned earlier was that my

predecessor, because he introduced this language that ended up getting amended, took away our authority to do a lot of things with -- with MACs. So part of what we were trying to do, although we had to accelerate when we got to 2002 and 2003, we had no choice. Part of it was to not shock the system, which had essentially been unmanaged. So we're trying to introduce these changes in a - I wouldn't say gradual, but we're trying to not hit people with so many things at once that we cause disruptions to service, or that, quite frankly, because it's a political environment, that it backfires on us, and we do have people going to the legislators, saying, basically, these people over at DHS are out of control, and have our authority to make the changes we thought were necessary taken away from us. So we didn't always do things initially as aggressively as we might have in the time frame we're talking about here, 2000, 2001. 2002, 2003, when we're starting facing budget deficits, even before then, we had started ramping up and doing preferred -- you know, our own internal preferred drug list for some categories. But we got very, very aggressive at that point. And so these days, as I mentioned earlier, we increased the use of generics because of the MAC program from about 50 percent when I started to 60 percent. It's now up to 69 percent. So -- you know -- anyway.

Q. But in these generics MACs that you're setting are shooting for a dollar amount spread -

A. Right.

Q. -- not necessarily for a correct percentage spread, right?

A. That's correct.

Q. And the correct percentage could be a thousand, could be 2,000, could be 1 percent, depending upon the starting cost of the product, right?

A. Yes, we are searching for a dollar spread, not a percent spread.

(Ex. AH, C. Wiberg Dep. at 356:19-360:13.)

United States' Response: The United States does not dispute that Mr. Wiberg testified as set forth above. Abbott has correctly, but selectively, quoted excerpts from Mr. Wiberg's testimony. The entirety of his testimony is the best evidence of its contents. Further responding, Mr. Wiberg's testimony was given in his individual capacity; he was not testifying on behalf of the State of Minnesota.

33. On April 21, 1999, Congressman Pete Stark of the U.S. House of Representatives Committee on Ways and Means sent a letter to HCFA Administrator Nancy-Ann Min DeParle that included the following statement:

> I urge you to take a simple and easy step to counteract an ongoing fraudulent practice by some pharmaceutical manufacturers that is costing Medicare and Medicaid hundreds of millions of dollars in excessive reimbursement payments. It is my understanding that HCFA and various antifraud units of the government have been working with a company known as First Data Bank to make available more accurate drug pricing information. If my understanding is correct, I request that you immediately issue written guidance to the States' Medicaid Programs approving their use of First Data Bank's agreed reporting of more accurate prices in calculating reimbursement amounts for certain injection, infusion and inhalation drugs and biologicals. I also request that you take similar action to insure that the Medicare carriers have access to and use the more accurate First Data Bank prices for the drugs and biologicals in question.

(Ex. AN at 3 (Abbott Ex. 136).) On April 26, 1999, DOJ's T. Reed Stephens faxed Mr. Stark's letter to Mary E. Riordan, Office of Counsel to the Inspector General, with the following note: "Letter from Congressman Stark to HCFA administrator last week. Stark is not aware of the *qui tam* but apparently is aware of our contacts with First Databank." (*Id.* at 2.) On April 27, 1999, Ms. Riordan faxed Mr. Stark's April 21, 1999 letter to Bob Niemann, CMS Drug Payment Policy Analyst (Medicare) and Larry Reed, Technical Director, CMS Medicaid Division of Pharmacy. (*Id.* at 1.)

United States' Response: The United States does not dispute that Abbott Ex. AN includes a copy of a letter from Congressman Peter Stark and that the above statement sets out a partial excerpt of text from that letter. The entirety of that document, however, is the best evidence of its contents. The United States disputes the materiality of the additional information in the above statement regarding distribution of copies of Congressman Stark's letter, but does not dispute that Exhibit AN indicates the letter was faxed to individuals referenced in the statement along with the notation quoted above.

34. On February 16, 2000, Patrick E. Lupenetti, a member of the NAMFCU Drug Pricing Team, sent a letter to Medicaid Pharmacy Directors concerning a national investigation by State and federal agencies regarding drug pricing and an effort to work with First DataBank to improve the accuracy and validity of pricing information provided for a

limited number of medications - generally infusion, inhalation, and injectable products. (Ex. AO (Abbott Ex. 137; Ex. AJ, H. Sullivan Dep. at 212:18-213:10.) The letter indicated that "the substance of this proposal has already been outlined to State Pharmacy Directors, particularly at your July 1999 national conference, in a presentation in which Assistant United States Attorney Reed Stephens, HHS-OIG Associate General Counsel Mary Riordan, Maryland MFCU Director Carolyn McElroy and most State Pharmacy Directors participated." (*Id.*)

United States' Response: The United States disputes the materiality of the information in the above statement. The United States does not dispute that Abbott Ex. AO is a copy of a letter signed by Patrick Lupenetti and that the above statement sets out a partial excerpt of text from that letter. The entirety of that document, however, is the best evidence of its contents.

35. On May 1, 2000, First Databank provided new average wholesale prices (hereafter, the "DOJ AWPs") for approximately 400 NDCs. (Ex. AP (Abbott Ex. 184); Ex. AQ, R. Berenson Dep. at 137:11-19.) The 400 NDCs represented 51 injectable, infusion, and inhalation drugs, including Abbott's vancomycin, dextrose, and sodium chloride. (*Id.*)

United States' Response: The United States does not dispute that Abbott Exhibit AP, which is a copy of HCFA Program Memorandum AB-00-86, states that on "May 1, 2000, First Data Bank provide [] new average wholesale prices to State Medicaid programs." The entirety of that document, however, is the best evidence of its contents. The United States disputes that Abbott's characterization of the information set out in the above statement appears in either of the two exhibits cited therein. The United States does not dispute that a list of drugs and corresponding AWPs was appended to Program Memorandum AB-00-86 when it issued.

36. On September 2001, the Office of Inspector published a report, titled "Medicaid's Use of Revised Wholesale Prices" (OEI-03-01-00010), that analyzed whether the State Medicaid programs were utilizing the DOJ AWPs. (Ex. AR (Abbott Ex. 95.) The report contained a chart that purported to show whether each state "Uses Revised Prices for Pharmacy Drugs," "Uses Revised Prices for Physician Drugs," and "Subtracts Discount for Revised Price." (*Id.* at 10-11.) The chart indicated that 20 states did not use the DOJ AWPs for any Pharmacy Drugs, and another eight Medicaid programs (Alabama, D.C., Idaho, Kansas, Ohio, Oregon, Texas, and Wisconsin) that did not use the DOJ AWPs for certain drugs. (*Id.*)

United States' Response: The United States does not dispute that the Office of Inspector published a report, titled "Medicaid's Use of Revised Wholesale Prices" (OEI-03-01-00010) in September 2001 and that the purpose stated in the report was to "describe[] State Medicaid Agencies' use of revised average wholesale prices for certain prescription drugs" and that there was a chart appended to the report. The entirety of that document, however, is the best evidence of its contents. The appended chart contains additional notational information regarding the states' use of revised average wholesale prices indicating, *inter alia,* that particular states, in 2000-2001, did not use revised prices for many of the affected drugs because the state relied on methods other than average wholesale price as its primary reimbursement methodology, no longer used revised prices for certain products, used contractors for which revised prices were not available, or did not use revised prices for drugs with a State maximum allowable cost.

37. In its project to assist Dr. Duggan with information on how the state Medicaid programs paid providers for dispensing drugs, Myers & Stauffer also analyzed the states's use of the DOJ AWPs. Myers and Stauffer found five states (Delaware, Idaho, Indiana, Oklahoma, and Pennsylvania) that OIG's report indicated were utilizing the DOJ AWPs, but for which they were unable to verify use of the DOJ AWPs, and another two states (Illinois and Montana) which eventually stopped using the DOJ AWPs. (Ex. AS.) OIG's report identified four states (Kentucky, Minnesota, Missouri, and North Dakota) that "used the DOJ AWPs at one time, but no longer do[] so." (Ex. AR at 10-11 (Abbott Ex. 95).)

United States' Response: Objection, the above statement is unduly vague. The United States disputes the materiality of the above statement. The United States does not dispute that Abbott Exhibit AR is a copy of an OIG report titled "Medicaid's Use of Revised Wholesale Prices" (OEI-03-01-00010) or that the report sets out information regarding states' use of average wholesale price information compiled by the Department of Justice. The entirety of that document, however, is the best evidence of its contents. The United States does not dispute that Abbott Exhibit AS consists of pages developed by Myers and Stauffer summarizing state Medicaid methodologies used to determine payment amounts for drugs, or that this information

was provided to Dr. Duggan in connection with his damage calculations in this case. The entirety of that document, however, is the best evidence of its contents. It is unclear from the statement whether Abbott is attempting to state a conclusion or inference based on the two documents that is not otherwise expressed on the face of the documents. In the event that Abbott has attempted to do so, the United States disputes such conclusion or inference.

38. Missouri is one of a number of states that implemented the DOJ AWPs, but later reversed its decision. In June of 2002, Missouri's Office of State Auditor wrote a performance audit titled "Cost Containment for State Drug Expenditures." (Ex. AT.) The report contained a discussion of Missouri's use of the DOJ AWPs, including the following language:

> Within 2 months of Department of Justice notice of the more accurate average wholesale prices, Utah officials began using the lower drug prices with new dispensing fees. With the help of infusion specialty providers, Utah officials categorized the 437 drugs into 5 groups appropriate to the preparation and overhead costs for the product. The new dispensing fees set up for drugs in 4 of the 5 categories ranged from $8.90 to $33.90 per prescription.
>
> Missouri officials initially implemented the more accurate prices for provider reimbursement using the normal $4.09 dispensing fee, which was not designed to cover these drugs. Division officials reversed the decision after home infusion providers threatened to cease services due to insufficient dispensing fees. Provider personnel admitted the former reimbursement rates exceeded their product acquisition costs, but they used the excess reimbursement to offset the higher dispensing costs of home infusion drugs. Division officials indicated they plan to use these lower prices again after determining adequate compensation for home infusion services. While no implementation date has been set, the Division Director stated the necessary changes to implement these prices would be part of the division's fiscal year 2004 budget proposal.

(*Id.* at 9.)

United States' Response: The United States does not dispute that Abbott Exhibit AT appears to be a performance audit by the State Auditor for Missouri bearing the title "Cost Containment for State Drug Expenditures" and that the partial excerpt of the text quoted in the

statement appears on page 9 of the 23 page report. The entirety of that document, however, is the best evidence of its contents. The United States disputes that materiality of the quoted text.

B. Medicare

39. In June of 1991, HCFA published a proposed rule relating to Medicare Part B reimbursement for drugs administered incident to a physician's service. It provided that "we are proposing that we will instruct all carriers to base payment for drugs on 85% percent of the national average wholesale price of drug (as published in RedBook and similar price listings), but we welcome comments regarding the appropriate discount." (Ex. AU (56 Fed. Reg. 25792 (June 5, 1991) at 2, Abbott. Ex. 298).)

United States' Response: The United States disputes the materiality of the above statement but not the facts stated therein.

40. HCFA's proposal to base Medicare Part B drug payment at 85% of AWP for drugs furnished incident to a physician's service was not implemented. Instead, HCFA implemented a payment regulation whereby Medicare Part B payment for multiple source drugs and biologicals was calculated as the "lower of the estimated acquisition cost or the national average wholesale price of the drug." (Ex. AV (42 C.F.R. § 405.517, Abbott Ex. 38).) This reimbursement level was effective as of November 25, 1991 and remained at this level until Congress enacted the Balanced Budget Act of 1997, which set payment for drugs paid under Medicare Part B at 95% of AWP. (Ex. AW, Portion of BBA 1997, Abbott Ex. 201).)

United States' Response: Objection, legal conclusions regarding regulatory or statutory intent are not resolved as factual statements pursuant to Fed. R. Civ. P. 56. Further, the content of a bill proposed by the President and the action or inaction of Congress are matters documented in the formal legislative record, which is not included in the statement. Accordingly, the United States disputes the materiality of the above conclusory statement but not the facts stated therein.

41. In 1997, the Clinton Administration's budget proposed that Medicare reimbursement for drugs be based on a the lowest of the following:

> (a) the physician's, supplier's, or other person's actual acquisition cost, as specified in paragraph (2);
> (b) the average wholesale price, as specified by the Secretary;
> (c) the median actual acquisition cost of all claims for the drug or biological for the 12-month period beginning July 1, 1998, adjusted annually and effective on January 1 of each year

> beginning with 2000; and
> (d) the amount otherwise determined under this part, less the applicable deductible and coinsurance amounts.

(Ex. AX (March 2, 1998 Fax from Maureen Adloph Furletti to R. Vito Including Language from FY 1998 budget, Abbott Ex. 203).) This language was again included in President Clinton's FY 1999 budget. (*Id.*) Congress enacted neither of these proposals. (Ex. AW (Portion of BBA 1997, Abbott Ex. 201); Ex. AY, N. DeParle Dep. at 153:20-154:07).)

United States' Response: Objection, legal conclusions regarding legislative intent are not resolved as factual statements pursuant to Fed. R. Civ. P. 56. Further, the content of a bill proposed by the President and the action or inaction of Congress are matters documented in the formal legislative record, which are not included in the above statement. Moreover, the United States disputes the materiality of provisions in proposed, as distinct from enacted, legislation. The United States does not dispute that Ms. Furletti sent Mr. Vito a fax on March 2, 1998, containing draft language relating to health care reform proposals. The 1997 BBA referenced in the statement set reimbursement at 95% of the average wholesale price. As Judge Saris has ruled, the term average wholesale price in the Medicare statute should be construed pursuant to is plain meaning language. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 460 F. Supp. 277, 287 (D. Mass 2006). The Court's ruling and the statute are consistent with the Clinton proposal which sought to pay at acquisition cost, net of discounts and rebates.

42. On February 13, 1998, Bill Thomas, Chairman of the Subcommittee on Health, and Bill Archer, Chairman on the Committee on Ways and Means, wrote HCFA Administrator, Nancy DeParle. The letter included the following statements:

> As you may know, the Balanced Budget Act of 1997 included a provision reducing the Medicare payment for drugs to 95 percent of average wholesale price. The Congress adopted this approach instead of the Administration's proposal to pay for drugs on the basis of acquisition cost.
>
> We are concerned that this proposal is intended to require physicians to bill Medicare for drugs at the acquisition cost. We would view any such attempt by HCFA to impose acquisition costs in direct conflict with Congressional intent and

would strongly oppose such a response.

Ex. AZ (Abbott Ex. 207).)

United States' Response: Objection, legal conclusions regarding legislative intent are not resolved as disputed or undisputed factual statements pursuant to Fed. R. Civ. P. 56. The United States does not dispute that Congressman Archer sent a letter to Ms. DeParle in February 1998. The United States disputes any effort to impute the Congressman's personal view to all of Congress. Members of Congress that closely observed Abbott's individual price reporting conduct came to the conclusion that it was fraudulent and inconsistent with Congressional intent when enacting the 1997 BBA. On October 31, 2000, Abbott's Miles White received a letter from Congressman Fortney Pete Stark which stated, among other things, the following:

- "You should by now be aware of Congressional investigations revealing that Abbott has for many years reported and published inflated and misleading price data and has engaged in other deceptive business practices. This letter is a call for your company to immediately cease overcharging taxpayers and jeopardizing the public health." (Lavine Decl. at Ex. 66 (Stark Oct.31, 2000 Letter to Miles White at p. 1)).
- "The evidence amassed by Congress clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs." *(Id.)*.
- "Contrary to Abbott's recent assertions in the national media, the price manipulation conduct was in no way required by or consistent with existing reimbursement laws or policies. Indeed, Abbott did not falsify published prices in

connection with other drugs, where sales and market penetration strategies did not include arranging financial 'kickbacks' to health care providers." (*Id.).*

- "Another example of Abbott's price manipulation concerns the IV antibiotic Vancomycin, the drug of last resort in combating many life threatening infections . . . Abbott's apparent price manipulation created a financial incentive for doctors to increase their usage of Vancomycin, at the very same time that overutilization of the drug created a health crisis. This is an especially reprehensible misuse of Abbott's position as a drug manufacturer." *(Id*. at 2, 4).
- "I urge Abbott to immediately cease reporting inflated and misleading price data. Such action places the nation's health care at great risk and overcharges taxpayers. Based on the evidence collected, Abbott should make arrangements to compensate taxpayers for the financial injury caused to federally funded programs." *(Id*. at 7).
- "I would appreciate your sharing this letter with your Board of Directors and I particular the Board's Corporate Integrity Committee." (*Id*.).

43. On August 5, 1997, Congress passed the Balanced Budget Act of 1997 which set Medicare reimbursement at 95% of average wholesale price. (Ex. AW (Abbott Ex. 201).)

United States' Response: The United States does not dispute the above statement. As Judge Saris ruled, the term average wholesale price in the Medicare statute should be given a plain meaning reading. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 460 F. Supp. 277, 287 (D. Mass 2006).

44. In December 1998, CMS sent a Program Memorandum to its fiscal intermediaries and carriers implementing the provisions of the Balance Budget Act of 1997. The memorandum contained the following statements:

> The purpose of this program memorandum (PM) is to furnish you with instructions needed to implement the Code of Federal Regulations (CFR), 42 CFR 405.517, as amended in the Federal Register (FR) in 63 FR 58849. This section

> of the regulations specifies that drugs and biologicals be paid based on the lower of the billed charge or 95% of the average wholesale price (AWP) as described below.
>
> Drugs and biologicals not paid on a cost or prospective payment basis are paid based on the lower of the billed charge or 95 % of the AWP as reflected in sources such as the Red Book, Blue Book, or Medispan

(Ex. BA at 1) (Abbott Ex. 233).)

United States' Response: The United States does not dispute that CMS (then HCFA) issued the program memorandum referenced in the statement nor that it contained the language quoted above. The United States disputes any implication that the program memorandum implemented a policy intended to pay inflated amounts for drugs or that the memorandum sanctioned the reporting of false or fraudulent pricing to the compendia referenced in the statement.

45. On September 8, 2000, CMS sent a program memorandum to its intermediaries and carriers with the subject "An Additional Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program." (Ex. AP (Abbott Ex. 184).) The memorandum contained an attachment that detailed prices for approximately 400 National Drug Codes (NDCs). CMS indicated the prices were "an alternative source of average wholesale price data for certain drugs, which has recently become available to HCFA," provided by the DOJ and National Association of Medicaid Fraud Control Units ("NAMFCU"). (*Id.*) The memo states that "[t]he DOJ has indicated that these are more accurate wholesale prices for these drugs." (*Id.*) The memo also states that "[o]n May 1, 2000, First Data Bank provided these new average wholesale prices to State Medicaid Programs. Some States have already implemented these new average wholesale prices while others have not." (*Id.*)

United States' Response: Undisputed..

46. In an undated memorandum, Michael Hash, Deputy Administrator of HCFA, wrote to Kevin Thrum, Deputy Secretary of Health and Human Services, regarding "Medicare Payments for Drugs Using Department of Justice Data-INFORMATION." The memorandum states: "*Finally, we also have received a revised opinion from OGC indicating that HCFA can require carriers to use the DOJ data, even without rule making*. This is because the data is characterized by DOJ as more accurately reflecting average wholesale prices." (italics and emphasis in original) (Ex. BB (HHD340-0031-0034).)

United States' Response: The United States disputes the above statement. There is no evidence that the draft memorandum referenced in the above statement was actually drafted by Mr. Nash or distributed to Mr. Thrum. To the extent this statement intends to make such representations, it is disputed. Moreover, the document, on its face, appears to be a non-final draft version of a memorandum. The United States does not dispute that the draft document exists or that it was produced by CMS in this case.

47. When Abbott requested a copy of both the revised and original legal opinions referred to in Deputy Administrator Hash's memorandum, DOJ stated: "We have been unable to locate any OGC document containing this opinion and, based on our inquiries, now believe that the referenced opinion was conveyed orally by OGC staff." (Ex. BC at 2 (March 13, 2009 Letter from Draycott to Torborg).)

United States' Response: The United States disputes the materiality of the above statement but does not dispute that Abbott sought to obtain privileged communications between CMS counsel and agency officials.

48. Congress passed the Benefits Improvement and Protection Act of 2000 ("BIPA"), which prohibited "lowering the payment allowances based on a change in methodology." (Ex. BD (May 3, 2001 Program Memorandum from HCFA to Carriers and Intermediaries, Abbott Ex. 1010).) HCFA informed the carriers and intermediaries that they could not "reduce the payment allowance from 95% of AWP." HCFA instructed carriers to "[u]se the established methodology . . . for determining payment allowances for drugs and biologicals . . . and use you usual source for AWP. Do not use any alternative sources of data for average wholesale prices for these items." (*Id.*)

United States' Response: Objection, legal conclusion regarding legislative intent are not resolved as disputed or undisputed factual statements. Notwithstanding this objection, the United States disputes this statement which mischaracterizes the legislation and the purpose of the moratorium. As stated in the program memorandum, the purpose was to give the General Accounting Office time to review Medicare payment policies and to make specific recommendations to the Secretary and to Congress regarding how to revise drug payment methodologies. *See* Abbott Ex. BD (May 3, 2001 Program Memorandum from HCFA to

Carriers and Intermediaries). The GAO later recommended that:

> Establish Medicare payment levels for part-B prescription drugs and their delivery and administration that are more closely related to their costs. Payments for drugs should be set at levels that reflect actual market transaction prices and the likely acquisition cost to providers.

(Lavine Decl. at Ex. 60 (Payments for Covered Outpatient Drugs Exceed Providers' Costs, GAO-01-1118, Sept. 21, 2001)).

49. In 2003, Congress passed the Medicare Modernization Act, which maintained payment for vaccines and infusion drugs administered through durable medical equipment at 95% of AWP. (Ex. BE (Portions of the Medicare Modernization Act of 2003 at 23, Abbott Ex. 194).) This payment methodology for vaccines and infusion drugs remains in effect today. Thomas Scully, the CMS Administrator from 2001-2003, testified that the exemption from the new ASP methodology for infusion drugs administered through DME, such as the products at issue in this litigation, was intended to "freeze" in a level of "cross-subsidy." (Ex. BF, T. Scully Dep. at 366:12-367:10.) He testified:

> Q. So it would appear that Congress, at least for these drugs and in that setting of home infusion has determined to continue to subsidize the provision of the services by overpaying for the drugs, correct?
>
> MR. GOBENA: Object to the form. The legislation speaks for itself.
>
> MR. BREEN: Objection to the form.
>
> BY MR. DALY: You can go ahead.
>
> A. Yes. I was surprised to see this. I forgot we did it. It was certainly never discussed by members. I'm sure the staff–staff person who wrote it works with me at Alston & Bird, so I'll go back and ask him, but I'm sure that it's probably, they froze it to freeze it, and some level of cross-subsidy apparently. I'm not sure what the congressional intent there was, but I think it was Senator Grassley's staff that did that provision. So I had totally forgotten we did it. That it was in the bill. It wasn't something that was widely discussed at all.

(Ex. BF, T. Scully Dep. at 366:12-367:10.)

United States' Response: Objection, legal conclusions regarding legislative intent are not resolved as factual statements pursuant to Fed. R. Civ. P. 56. Further, the content of a proposed bill and the action or inaction of Congress are matters documented in the formal legislative record, which is not set out in the above statement. The deposition testimony of a fact witness in this case concerning the content of such legislative action or inaction is not relevant or admissible. *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004). Notwithstanding this objection, the United States disputes this statement. As noted both in this excerpt cited by Abbott and elsewhere, Mr. Scully had no recollection about the MMA provisions related to home infusion services. He testified above that he was "not sure what the congressional intent there was." Abbott Ex. BF, Scully Dep. at 367:5-6. Just before the testimony excerpted, Mr. Scully informed counsel for Abbott he had no recollection about the 2003 MMA provisions regarding vaccines and home infusion:

BY MR. DALY:

Q. And so at least for the drugs that are subject to this carveout in the home infusion setting, Congress has kept the reimbursement of those drugs at 95 percent of AWP as of –

A. As of October 2003.

Q. That's correct, isn't it?

A. I guess it is. That's what the statute says. Another piece of sausage. I **have just forgotten that we did that, to be honest with you**, which I assume is why they don't have a dispensing

fee for anything but respiratory drugs, because they

didn't do that for respiratory drugs.

(Id. at 366-367). (emphasis added). The witness did not remember the statutory provision at issue and did not know the congressional intent behind it. Abbott cites no legislative history supporting its contention that Congress intended any continued use of AWP to "freeze in a cross-subsidy." This unclear speculation by this witness does not support that conclusion. As noted above, the only congressional scrutiny of the specific Abbott conduct at issue in this case resulted in correspondence from a member of Congress accusing Abbott of fraud.

III. FEDERAL AND STATE TESTIMONY CONCERNING AVERAGE WHOLESALE PRICE

A. Federal Testimony

50. HCFA Administrators from the relevant time period testified that they understood AWP to refer to the price published in the compendia.

(a) Bruce Vladeck, CMS Administrator from 1993-1997, testified:

Q. And the AWP in that legislation [Balanced Budget Act 1997] did you understand that in the same way you understand AWP in the regulation from 1992?

A. Yes.

Ms. Brooker: Objection. Form.

Q. And so that would refer to a published average wholesale price. Correct?

A. That was our understanding of it, yes.

(Ex. BG B. Vladeck Dep. at 278:18-279:03.)

(b) Nancy Ann Min-DeParle, CMS Administrator from 1997-2000, testified:

Q. If you look at the bottom of the first page, the Congressman writes, quote: The Congress in 1997 instructed the department to base reimbursement for drugs on 95 percent of AWP; a term widely understood and indeed defined by department manuals to

reference amounts reflected in specific publications.

First of all, is that a correct statement of what Congress did in 1997?

Ms. Yavelberg: Objection to form.

A. Yes.

(Ex. AY, N. DeParle Dep. at 314:08-18.)

(c) Thomas Scully, CMS Administrator from 2001-2003, testified:

Q. And was it you understanding that the, that the AWP that CMS was using as the benchmark for reimbursement was the AWP that was published in the compendia?

A. For the most part, it was my understanding that the standard practice was that 95 percent of AWP was the AWP that was published in the Red Book.

Q. And that's what you understood the law and regulations to require?

A. That's what I understand at the time. At the time, that's what I believe the law and regulations required.

(Ex. BF, T. Scully Dep. at 105:17-106:06.)

* * *

Q. Okay. Now, this was a complaint that was signed the 22nd day of August, 2006, and on paragraph 40, in the first sentence, it says, AWP is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail customer, who then administers it to a patient; do you see that?

A. Yes.

Q. That's not what AWP was viewed as, that's not the view of CMS as to what AWP was, is it?
MR. NEAL: Objection as to from.

By MR. ESCOBAR:

Q. Is it?

MR. NEAL: This is not a 30(b)(6), this is not a 30 (b)(6) deposition. You can answer.

A. No, I don't think that's what AWP is commonly considered to be, I think that's an inaccurate description.

Q. In fact, that's a completely inaccurate statement of AWP; right?

MR. NEAL: Objection as to form.

A. I think it's probably a poor description, yes.

Q. Because it's not accurate?

A. Yes.

(*Id.* at 709:20-711:02.)

* * *

Q. All right. Have you ever used average wholesale price to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail customer?

A. No.

MR. GOBENA: Object to the form.

Q. Have you ever heard anybody else use AWP to refer to the price of which a pharmaceutical firm or a wholesaler sells a drug to a retail customer?

MR. GOBENA: Object to the form.

A. No.

(*Id.* at 900:16-901:06.)

United States' Response: Objection, this statement is unduly vague because it does not indicate (a) whether "AWP," is meant to apply to the term as used in regulations and statutes or, alternatively, to a category of information published in private compendia (*see, e.g.*, 68 Fed. Reg. 50,429 (Aug. 20, 2003) (using the term "list AWP" to refer "to the AWP published in

commercial compendia such as Red Book, Price Alert and Medispan")), and (b) whether defendant contends the that former "HCFA Administrators" whose depositions are quoted should be considered to have expressed official, as opposed to personal views, regarding their understanding of the term "AWP". To the extent the above statement concerns the personal opinions of former HCFA Administrators, the United States disputes the relevance of those opinions in this case. *See United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004) (personal views of agency officials "are irrelevant" when interpreting a regulation). Moreover, any personal view expressed by a former administrator during a deposition may not be construed as the official position of a federal agency. *Id.* ("agency interpretations are relevant only if they are reflected in public documents"). The United States further disputes the materiality of the statement based on the rulings by the District Court construing the term "AWP" pursuant to its plain language and as a matter of law. *See In Re Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 278 (D. Mass. 2006). The United States does not dispute that the individuals whose names appear in the statement gave the testimony quoted therein.

51. Federal officials involved in Medicare and Medicaid drug payment policy, OIG officials, and Medicare Carriers similarly testified that the term "AWP" referred to prices in the compendia, such as:

> (a) Robert Niemann, former CMS Drug Payment Policy Analyst, testified:
>
> Q. What did you understand Congress to be referring to in Exhibit Abbott 201 when Congress referred to 95 percent of the average wholesale price?
>
> A. I guess–I don't remember–I don't remember the content of any conversations I had with Congressional staffers that would inform on the answer to that question, but whatever they had in mind, this instruction here seems to state that same language that we've discussed ad nauseam before now as reflected in sources such as the Red Book, Blue Book or Medispan.

(Ex. BH, R. Niemann at 366:10-21.)

> (b) Charles Booth, former Director of HCFA's Office of Payment Policy,

testified:

A. I came to realize, as I indicated earlier, sometime in I believe 1985 or early 1986 that AWPs were not the prices being paid by physicians and pharmacists for drugs.

Q. When you came to that realization in 1985 or '86 did you undertake any steps to change the way states were reimbursing for drugs?

A. Well, as I indicated earlier we stopped approving state plans that used AWP as the mechanism for pricing drugs. We didn't approve state plans that suggested that AWP was their payment methodology.

Q. And the reason is, just so I'm clear, is because you as the director of office of payment policy had realized AWP did not reflect actual acquisition costs?

A. Well, I think it's wider than a personal realization on the part of the director of the office of payment policy. But clearly I recognized that to be the case.

Q. When you say it was wider, can you explain what you mean by that?

A. Well, again, the individuals who adjudicated the payment issues for state plans on my staff had clearly come to this position before I realized that it was an issue.

(Ex. BI, C. Booth Dep. at 442:16-443:19.)

Q. During this time period from 1991 to 1997 what was your understanding of what AWP referred to?

A. AWP was what the manufacturers chose to put in the compendia.

Q. At any time in this time period did you understand AWP to refer to a calculated average of wholesale prices that were charged to physicians or other purchasers of these products?

A. No.

(*Id.* at 518:10-18.)

Q. Is that consistent with your understanding in 1994 that the AWP was a published price that could be found in these compendia?

MR. GOBENA: Objection, form.

A. Yes. I believe we consistently advised carriers that these were the most frequently used published sources for AWP.

(*Id.* at 320:22-321:6.)

(c) Kathleen Buto, former Director of CMS's Bureau of Policy Development, testified:

Q. Second-to-last sentence from the bottom in the paragraph. "Moreover." It states "Moreover, we are proposing for very high volume drugs the payment for the drug would be limited to the lower of the estimated acquisition cost of the drug as determined by us and specified in instructions to carriers or 85 percent of the national average wholesale price for the drug."
A. Right.

Q. What did you mean when you say "national average wholesale price for the drug"?

A. AWP.

Q. As reflected in Red Book or a similar-

A. Yes, or some other resource.

* * *

Q. But if we used the average wholesale price method it would be based on what was published in the Red Book, correct?

A. Yes. That was made clear later in one of the other documents, that it was based on the published. . . .

(Ex. BJ, K. Buto Dep. at 257:19-258:11, 306:2-7.)

(d) Elizabeth Richter, former Acting Director of the Center for Medicare Management, testified:

Q. And you'll agree with me that from Louis B. Hays through Dr. Vladeck through Ms. Min DeParle through Mr. Scully, through the information you've looked at no administrator thought that published AWPs represented the average price at which wholesalers sold drugs to their customers, correct?

MR. DRAYCOTT: Objection.

A. That is what their testimony says, yes. But again, without seeing the full context. But yes, that's what it says.

(Ex. BK, E. Richter Dep. at 68:3-13.)

* * *

Q. Vaccines are paid based upon the current published AWPs, correct?

A. Yes.

Q. Currently is the agency undertaking any effort to determine what the average price is at which wholesalers are selling drugs to their customers other than by looking it up in compendia?

MR. DRAYCOTT: Objection. You can answer.

A. Not to my knowledge, no.

Q. So do you understand today to be the statutory command to pay average wholesale price to be satisfied by looking it up in the compendia?

MR. DRAYCOTT: Objection.

A. Yes.

(*Id.* at 69:3-19.)

Q. At any time have you ever referred to the AWP for a number and intended to communicate thereby that the average price at which customers are buying the product is that amount?

A. No.

(*Id.* at 152:9-13.)

(e) Robert Vito, Office of the Inspector General, Regional Inspector General, testified:

Q. . . . When you used the term "average wholesale price" in your work at OIG, did you equate it with the prices that were published in Red Book and other price listings?

MR. AZORSKY: Objection to form–

MR. NEAL: Objection as to form; asked and answered.

A. I–I–I–I have said that AWP is what the Medicare program based its reimbursement on and they were in the Blue– Blue Book and Red Book.

Q. Can you answer my question, yes or no?

MR. AZORSKY: Objection to–

BY MR. TORBORG: And just tell me if you can't. If you can't, that's fine –

MR. AZORSKY: Objection to form.

MR. NEAL: Same objection.

A. I'd like to hear the question one more time.

BY MR. TORBORG: When you use the term "average wholesale price" or "AWP" in your work at OIG, did you equate it with what was published in Red Book and similar price listings?

MR. AZORSKY: Objection to form.

MR. NEAL: Objection as to form.

MR. WINGET-HERNANDEZ: Objection.

A. I–I–I–I–I guess the answer's yes.

(Ex. BL, R. Vito Dep. at 145:20-147:6.)

(f) David Tawes, Director of the Medicare and Medicaid Drug Pricing Unit, testified:

A. I don't remember any specific conversations about EAC. The conversations would have been just that Medicare is required to pay 95 percent of AWP.

BY MR. TORBORG: And your understanding of that (AWP] relates to what was published in Red Book or other price listings, right?

MR. NEAL: Objection as to form. You can answer.

A. Yes.

(Ex. BM, D. Tawes Dep. at 141:14-142:2.)

(g) Larry Reed, Technical Director, CMS Medicaid Division of Pharmacy, testified:

Q. When you use the term average wholesale price, or AWP, what did you

mean it to refer to?

MS. MARTINEZ: Objection to form.

MR. HERNANDEZ: Objection to form. . . .

THE WITNESS: Okay. When we use average wholesale price, generally we will be using average wholesale price as reported by one of the pricing compendia.

(Ex. BN, L. Reed Dep. at 99:7-19.)

Q. The report states, "Within the pharmaceutical industry, AWP means non-discounted list price." Mr. Reed, was that consistent with your understanding of what the term 'AWP' meant in the pharmaceutical industry?

A. At this point in time? I wasn't working in the program at this point in time.

Q. When you started your position in 1990 on the Medicaid side working on prescription drug issues, was this sentence consistent with your understanding of what the term AWP meant?

A. To qualify that a little bit, if AWP meant the published price in a pricing compendia that the state would have referenced or used in a state plan amendment, then it would be–it would be my understanding that AWP would be more than the state should pay for the drug. In other words, AWP should be discounted.

Q. Was it your understanding that AWP referred to a non-discounted list price?

A. It's my understanding that AWP is a price, again, that was reported in the compendia that would be more than what a state would pay for a drug. I'm not quite sure if I would equate that with list price or what price I would equate that with.

Q. What does the term 'list price' mean? Are you familiar with that term in this industry?

A. I've heard it mentioned on many occasions.

Q. What is your understanding of what it means?

A. A list price would be a full price that a purchaser may or may not obtain a drug at.

Q. And you've heard the term AWP referred to or analogized to a sticker price on a car; is that fair to say?

A. I have heard that term, yes.

Q. And have you also heard the term average wholesale price being called ain't what's paid, right?

A. It look a long time to get to that joke, but we finally got there, yeah.

Q. Okay. When did you get to that joke?

A. For you to get to that joke–

Q. Yes.

A. –today.

Q. Okay. Yes, it is 3:30. When did you learn about that?

A. The saying has been around for a long, long time.

(*Id.* at 258:20-261:5.)

(h) Robert Berenson, former HCFA Deputy Administrator, testified:

Q. Do you ever remember hearing anyone else use it to mean that?

A. As I said earlier, I think there was a common understanding within the agency that AWP referred to the prices in these compendia and that they deviated from actual acquisition prices and that's how we sort of viewed AWP.

(Ex. AQ, R. Berenson Dep. at 72:19-73:03.)

(i) Linda Ragone, Deputy Regional Inspector General for OIG, testified:

Q. Okay. Did you understand Congress to be directing HCFA to pay 95 percent of the published AWP?

MR. DRAYCOTT: Objection.

A. I believe when I read that that–well, I don't–I don't have it in front of me, so I believe that it was supposed to be 95 percent of average wholesale price.

BY MR. COOK: And you understood that to be what is published in Red Book, Blue Book, Medispan, right?

A. That's what I took it to mean.

(Ex. BO, L. Ragone Dep. at 552:1-12.)

(j) Rena Clark, 30(b)(6) Witness for Wisconsin Physician Services ("WPS"), a Medicare Part B Carrier, testified:

Q. In your work at WPS has the term average wholesale price been synonymous with what–the prices that would be contained in the Red Book or other price listings?

MR. HENDERSON: Objection.

THE WITNESS: Yes.

MR. TORBORG: When you thought of AWP, you thought of Red Book; is that fair to say?

MR. HENDERSON: Objection.

THE WITNESS: That's true.

(Ex. BP, R. Clark Dep. at 67:18-68:6.)

Q. So if I understand correctly, in order for you to be able to use an AWP price, it has to specifically come from Red Book?

A. It doesn't have to specifically come from Red Book, but it has to specifically come from a published compendia. And a published compendia is something that's published that-I guess it's not the manufacturer saying, we've raised the price; this is what our new Red Book amount is. It comes from the Red Book publication or Blue Book or Medispan or whatever.

Q. So if someone from Abbott had called you up and said, Ms. Clark, the AWP for Vancomycin, for example, should be $5, instead of what it was recorded in Red Book, could you use that?

A. No.

Q. And why is that?

A. Because it would not have been a published source

(*Id.* at 125:3-21.)

Q. Okay. Is it your understanding that the law required that a carrier such as WPS use AWP prices found in published sources such as Red Book, Blue Book, or Medispan?

A. Yes.

(*Id.* at 160:4-8.)

(k) Sue Gaston, Former CMS Health Insurance Specialist, testified:

Q. Do you remember–when you used the word or the phrase average wholesale price, what did you understand it to mean?

MS. ALBEE: Objection, form.

A. Average wholesale price was a price that we used along with the direct price or the WAC price for determining the FULs. It really wasn't our place–for me when I'm working on the FULs–to get into defining it. I'm looking at it for FULs purposes.

Q. And where did you look to get average wholesale prices?

MS. MARTINEZ: Objection, form.

A. The three prices the average wholesale price, direct price and the wholesale acquisition cost, was provided to us by the compendia sources.

Q. That would be Blue Book, Red Book and Medi-Span?

A. Correct.

(Ex. BQ, S. Gaston Dep. at 144:17-145:13.)

United States' Response: Objection, this statement is vague because it does not indicate (a) whether "AWP" is meant to apply to the term as used in regulations and statutes or, alternatively, to a category of information published in private compendia (*see, e.g.*, 68 Fed. Reg. 50,429 (Aug. 20, 2003) (using the term "list AWP" to refer "to the AWP published in commercial compendia such as Red Book, Price Alert and Medispan")), and (b) whether the former "federal officials" whose depositions are quoted are alleged to have expressed official, as opposed to a personal, views regarding their understanding of the term "AWP." To the extent

the above statement concerns the personal opinions of present and former HCFA employees, the United States disputes the relevance of those opinions in this case. *See United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004) (personal views of agency officials "are irrelevant" when interpreting a regulation). Moreover, any personal view expressed by a federal employee, whether current or former, during a deposition may not be construed as the official position of a federal agency. *Id.* ("agency interpretations are relevant only if they are reflected in public documents"). The United States further disputes the materiality of the statement based on the rulings by the District Court construing the term "AWP" pursuant to its plain language and as a matter of law. *See In Re Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 278 (D. Mass. 2006). The United States does not dispute that the individuals whose names appear in the statement gave the testimony quoted therein.

52. Dr. Bruce Vladeck, HCFA Administrator from May 1993 to September 1997 testified that he reviewed articles published *Modern Healthcare* magazine during the 1980s which discussed discounts on basic infusion products and sterile supplies as high as 99%. (Ex. BG, B. Vladeck Dep. at 144:22-145:19.) Dr. Vladeck provided the following testimony:

> A. Well, I actually–in the 1980s, I believe, when I was first becoming involved in some of these issues in health care economics was the first development of hospital group purchasing operations, and I recall–and the first widespread circulation of the–of "Modern Healthcare," the magazine, and I recall monthly headlines in "Modern Healthcare" about group purchasing operations being–achieving discounts of 98 and 99 percent in their purchase of basic infusion products and sterile supplies. So, my perception was that on the supply market, which, again, I understood and still would contend is actually a separate market from the pharmaceutical market that list prices, are essentially entirely meaningless and that only the weakest and smallest scale buyers pay anything close to it.
>
> Q. And so, as of 1993, for example, would you be surprised if a single bag of sodium saline solution sold to a provider who bought maybe five would pay $10 per bag, and a large purchaser who bought a very large volume would pay less than a dollar?
>
> MS. BROOKER: Objection. Form.

A. I would not have been surprised.

(*Id.* at 145:09-146:12.)

United States' Response: Objection, this statement is vague because it does not indicate whether Dr. Vladeck, whose testimony is quoted, is alleged to have expressed an official, as opposed to a personal, view regarding the subject matter of his deposition testimony. To the extent the above statement concerns the personal views of Dr. Vladeck, the United States disputes the relevance of those views in this case. *See United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004) (personal views of agency officials "are irrelevant" when interpreting a regulation). Moreover, any opinion expressed by a former administrator during a deposition may not be construed as the official position of a federal agency. *Id.* ("agency interpretations are relevant only if they are reflected in public documents"). The United States further disputes the materiality of the statement based on the rulings by the District Court construing the term "AWP" pursuant to its plain language and as a matter of law. *See In Re Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 278 (D. Mass. 2006). The United States does not dispute that Dr. Vladeck gave the testimony quoted by defendant.

53. On July 5, 1987, the Lexington Herald-Leader published an article titled "Drug Industry Overcharging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars." (Ex. BR.) The article stated that "Medicaid programs across the country are making millions of dollars in overpayments because of flaws and abuses in the way they buy prescription drugs for the poor." (*Id.* at 1.) The article stated that "[t]he system is distorted even further by drug companies that publish prices that are dramatically higher than the prices they actually charge pharmacies." (*Id.*) In one example, the article stated that as a result of a 1985 survey, Texas Medicaid officials learned that "one brand of penicillin . . . had a Red Book price of $100 'but pharmacists were buying it all day long for $30.'" (*Id.* at 7.) In another example, the article stated that Kentucky Medicaid officials "discovered that [an arthritic medication] was being sold to pharmacies for only 8.88 cents a tablet–47% below the published Average Wholesale Price" (*Id.* at 4.) The article also discussed a "sales technique called 'playing the spread,'" noting that a large "spread, or difference, between the [AWP] and the actual price" meant that "a pharmacist buying that drug could make a larger profit." (*Id.* at 4-5.) The article stated that some "companies actually advertised that they had a better spread," and that "many companies routinely list Average

Wholesale Prices and 'your price' in their catalogs to show the spread." (*Id.* at 5.) The article indicated that previous attempts to change the system had "met bitter resistance from the National Association of Retail Druggists" and other groups, who "led the fight to force the federal Health Care Financing Administration . . . to retreat from proposed changes in 1985 that came up after the inspector general's audit discovered the overpayments." (*Id.* at 8-9.)

The United States' Response: The United States does not dispute that on July 5, 1987, the *Lexington Herald-Leader* published an article "*Drug Industry Over Charging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars*." Abbott has paraphrased and in other instances selectively quoted from that article; the entirety of the article referenced is the best evidence of its content. The United States notes the article is and contains hearsay. The United States does not dispute that in 1987 pharmacies could purchase drugs at a discount from AWP. The United States disputes the relevancy of the article to Abbott's liability under the FCA, however. The article does not mention Abbott or refer to any of the Subject Drugs. Further, the "spreads" referred to in the article are much smaller than most of those created by Abbott for the Subject Drugs. Finally, language in the article itself indicates government disapproval of AWPs that exceeded providers' actual acquisition costs; such AWPs were considered to be "inflated," resulting in Medicare "overpayments." *See*, for example, Tab 73 at 1 (referring to "millions of dollars in overpayments because of flaws and abuses").

54. On June 5, 1991, HCFA published a proposal to change the methodology for reimbursing drugs under Medicare Part B to 85 percent of the national average wholesale price (AWP) of the drug as published in the Drug Topics Red Book and similar price listings. (Ex. AU at 1.) In connection with the proposed rule, HCFA requested the Office of Inspector General ("OIG") to conduct a study to "(1) determine the impact of paying dialysis facilities for drugs based on the proposed regulation and (2) obtain the necessary data to include payment for certain high volume separately billable dialysis-related drugs under the prospective composite rate." (*Id.* at 1.) In October 1992, the OIG published a report titled "Cost of Dialysis-Related Drugs." (Ex BS.) As part of its study, OIG pulled pharmacy invoices for drugs, including Abbott's vancomycin, to determine the "estimated acquisition cost" for each product. (*Id.*) OIG compared its estimated acquisition cost for vancomycin to the median published AWPs for four different manufacturers of vancomycin. (Ex. BT; Ex. BS at 6 (Abbott Ex. 82).) OIG determined that the estimated

acquisition cost of 500 ML of vancomycin was $5.00, while the median published AWP was $19.17. (*Id.* at 1, 2, 6.)

United States' Response: The United States disputes the materiality of the above statement. The United States does not dispute that on June 5, 1991, HCFA published a Notice of Proposed Rulemaking and that excerpts of text quoted above appear in the Notice. Nor does the United States dispute that in October 1992, the Office of Inspector General for HHS published a report with the title noted above.

55. The July 1980 edition of Modern Healthcare included an article titled "Hospitals Play Into Hands of Vendors Who Try to Break Group Contracts." (Ex. BU.) The article stated that "some hospitals are . . . joining groups to get prices down and then using these prices to get better offers from their current vendors." (*Id.* at 1.) The article published Abbott's committed volume contract bid prices submitted to Joint Purchasing Corp., a hospital purchasing group, for dextrose and sodium chloride. (*Id.* at 1.) The article stated that "[i]f all 17,000 beds participate, the [purchasing] group will get about an 80% discount off current list prices for [I.V.] solutions." (*Id.* at 2.)

United States' Response: The United States disputes the materiality of the above statement. The United States does not dispute that the July 1980 edition of Modern Healthcare included an article with the title noted above or that excerpts of text quoted above appeared in the article. The United States notes that the article is, and contains, hearsay.

56. In August 1994, at HCFA's request, the Office of Inspector General commenced an audit surveying AWP prices. (Ex. BV, P. Chesser Dep. at 66:1-9; 89:2-4.) The results of this study were published in a 1997 OIG report titled Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products. (*Id.* at 87:19-88:11; Ex. BW (Abbott Ex. 158).) The objective "was to develop a nationwide estimate of the discount below AWP at which pharmacies purchase generic drugs." (*Id.*) As part of its study, OIG "selected a random sample of 11 states" and collected over 9000 invoice prices for generic drugs. (*Id.*) Based on its audit, OIG "estimated that, on average, actual acquisition cost of generic drugs was 42.5 percent below AWP." (*Id.*) In its comments to the report, HCFA concurred with OIG's findings and stated that "[t]he findings shown in the report confirm the belief shared by many states that the pharmacy's actual generic drug acquisition costs are much less than the prices paid by many states to the pharmacies." (*Id.* at App. 3, Pg. 2.)

United States' Response: The United States disputes the materiality of the above

statement. The United States does not dispute that in or around August 1994, the Office of Inspector General for HHS commenced an audit surveying AWPs and in 1997 published a report with the title noted above. Nor does the United States dispute that partial excerpts of text quoted above appeared in the report. The United States disputes that the comments by HCFA concur in the findings, as opposed to the recommendations, stated in the report.

57. Paul Chesser was the OIG agent who analyzed invoices pulled in conjunction with the 1994 AWP study. He testified that he found "significant discounts" on injectable solutions–at a "90 plus percent" discount from AWP. (Ex. BV, P. Chesser Dep. at 626:6-630:12.) Mr. Chesser provided the following testimony:

> Q. Would it surprise you to see discounts in the 90 percent plus range for these injectables?
>
> A. No. It was very common.
>
> (*Id.* at 630:5-7.) Other work papers obtained for this 1994 study showed acquisition prices for the four drugs at issue in this litigation – Vancomycin, sterile water, sodium chloride, and dextrose. (Examples cited at Ex. BX.)

United States' Response: The United States disputes the materiality of the above statement. The United States disputes the assertion that Paul Chesser was an OIG agent or any implication that he was employed by the Office of Inspector General, Office of Investigations. The United States does not dispute that Mr. Chesser was employed by the Office of Inspector General, Office of Audit Services. The United States does not dispute that during his deposition Mr. Chesser testified as indicated in the partial excerpts quoted above. The entirety of the testimony referenced is the best evidence of its content.

58. On August 30-31, 1994, representatives from OIG, HCFA, and ten State Medicaid programs met in Richmond, Virginia to discuss OIG's plan to conduct a nationwide audit surveying the difference between the invoice price for drugs and AWP, for Medicaid providers. (Ex. BY, Abbott Ex. 581.) OIG prepared a "Record of Discussion" of that meeting. (*Id.*) OIG's Record of Discussion includes the following statement:

> They stated that we should include a fifth category of pharmacies to include non-traditional retail pharmacies such as hospitals, home

> IV, nursing homes, physicians etc . . . The State officials believed that these pharmacies purchased at substantially bigger discounts than traditional retail pharmacies.

(*Id.* at 2-3.)

United States' Response: The United States disputes the materiality of the above statement. The United States does not dispute that a "Record of Discussion" exists and indicates that the meeting described above occurred on the date referenced in the statement. Nor does the United States dispute that the Record of Discussion contains the text in the partial excerpt set out above.

59. Federal officials involved in Medicare Part B and Medicaid drug payment policy, as well as OIG officials, testified regarding their knowledge of spreads between acquisition cost and published AWPs, including:

> (a) Larry Reed, Technical Director, CMS Medicaid Division of Pharmacy, testified:
>
> Q. Did you have discussions about the significantly greater difference between AWP and acquisition costs for generic drugs as opposed to branded drugs?
>
> MS. MARTINEZ: Objection, form.
>
> MS. POLLACK: Objection, form.
>
> THE WITNESS: I believe we had those discussions.
>
> BY MR. TORBORG:
>
> Q. Who were those discussions with?
>
> MS. MARTINEZ: Objection, privilege.
>
> MR. TORBORG: We have to decide who the discussions were with before we can decide what privilege applies.
>
> MS. MARTINEZ: No, the discussions were within HCFA, and if they related to an anticipated decision by HCFA, then it would be privileged and then you would be instructed not to answer. If you had a discussion with somebody in the outside

that's not related to a policy decision like that, you can–you can answer.

THE WITNESS: I can't answer.

BY MR. TORBORG:

Q. So you had discussions within HCFA about the significantly greater difference between acquisition costs and AWP for generic drugs as compared to branded drugs, correct?

MS. MARTINEZ: Objection, form.

THE WITNESS: We did have those discussions.

BY MR. TORBORG:

Q. And I'm not permitted to probe your memory here today because you've been instructed not to answer, correct?

A. Correct.

(Ex. BN, L. Reed Dep. at 519:9-520:22.)

Q. I'm trying to . . . figure out what decision or policy those discussions related to.

A. The decision would be how to look at this and reviewing a state plan.

Q. And whether or not to approve or disapprove the plan?

A. That could be part of that decision.

Q. Which would ultimately determine how much providers were paid for drugs, correct?

A. Correct.

(*Id.* at 523:3-13.)

(b) Charles Booth, Former Director of Office of Payment Policy, testified:

Q. During this time period from 1991 to 1997 what was your understanding of what AWP referred to?

A. AWP was what the manufacturers chose to put in the compendia.

Q. At any time in this time period did you understand AWP to refer to a calculated average of wholesale prices that were charged to physicians or other purchasers of these products?

A. No.

MR. GOBENA: Object to the form.

Q. At any time were you ever fooled into believing that average wholesale price somehow was the same thing as acquisition cost?

MR. GOBENA: Objection to the form.

MR. WINGET-HERNANDEZ: Objection.

A. Was that a leading question?

Q. Yes, sir.

A. Fine. I did not believe that there was a relationship to any great extent between acquisition costs and AWP."

(Ex. BI, C. Booth Dep. at 518:10-519:8.)

Q. And so certainly nobody expressed to you an expectation that there would be some relationship between acquisition cost and AWP?

MR. GOBENA: Objection, form.

A. I certainly don't remember any.

Q. Did that change over time?

A. No.

(*Id.* at 310:9-15.)

Q. Was it the position within payment policy that AWP was inflated and overstated the price that providers actually paid for drugs?

MR. BREEN: Objection to form.

MR. GOBENA: Join.

A. Yes, by some percentage, and it of course varied by drug . . . .

(*Id.* at 236:17-237:1.)

(c) Sue Gaston, Former CMS Health Insurance Specialist, testified:

Q. And did you understand that the average wholesale price for multiple source drugs in particular was not a reliable indicator of the cost at which pharmacies and physicians purchased drugs?

MS. MARTINEZ: Objection to form.

MS. ALBEE: Objection to the form.

MR. WINGET-HERNANDEZ: Objection, form.

A. As I stated before, my understanding is that I looked at average wholesale price, direct price, wholesale acquisition costs, the prices that were available in the compendia, and generally speaking the average wholesale price was a higher price at that point others.

(Ex. BQ, S. Gaston Dep. at 218:2-14.)

(d) Robert Vito, Regional Inspector General, testified:

Q. For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60 to 90 percent below the so-called average wholesale price, or AWP, used in reimbursement claims. When did you become aware of the fact that there were–that generic drugs were being sold to providers at amounts 60 to 90 percent below average wholesale prices?

MR. NEAL: I'll object to the form of the question.

THE WITNESS: I think we became-I mean, of course, this article pointed it out, but I think we also, our work in albuterol sulfate, which is the generic, demonstrated some of those issues as well, as well as some of the other work that we have done here. I believe at this time Leucovorin was also a generic, so there were other generic products that we had seen and seen some pricing variations on.

BY MR. TORBORG:

Q. Do you recall discussions with CMS officials in this time frame about the fact that generic drugs were selling at amounts 60 to 90 percent below the so-called average wholesale prices?

MR. NEAL: Objection as to form.

THE WITNESS: I believe when we issued our reports, the reports pointed out that the products were selling below the–the AWP and that clearly some of the products were generic.

(Ex. BL, R. Vito Dep. at 490:9-491:18.)

(e) Kathleen Buto, former Director of CMS's Bureau of Policy Development, testified:

Q. That's right. Now, there's no doubt that as of 1991 HCFA knew that unmodified AWP, a hundred percent AWP, did not represent actual acquisition cost, right?

A. Yes.

Q. And there was no doubt that in 1991 HCFA knew that there was no predictable relationship between AWP and actual acquisition cost, right?
A. Based on the surveys from the IG, that's correct. That was our belief. Again, we didn't have independent data.

Q. Right. That was your belief at that time, right?

A. That's correct.

(Ex. BJ, K. Buto Dep. at 433:04-18.)

(f) Ben Jackson, Acting Director, Operational and Program Reviews, Health Care Financing Audit Division, Office of Inspector General, testified:

Q. Even though you were one of the leading people at OIG during the 1990s in this area no one even asked you whether you thought this lawsuit had any merit, right?

MR. AZORSKY: Objection, form.

A. No. But they wouldn't.

Q. Why wouldn't they want to hear what people who were there thought before they filed a lawsuit?

A. That's a good question. I mean, I think our reports kind of speak for themselves. I mean, the thoughts are in the reports, the writing of the reports. So, I mean, it's there. It is what it is.

Q. What do you mean by that?

A. Well, it's documented in these reports. I mean, we've got, what, eleven state reports in one batch and we've got eight in the next. We've got four roll-up reports and we've got follow-up reports to those. So, I mean, it's pretty well documented what the findings were, right? So --

Q. And the findings are that states are paying more than acquisition cost, particularly for generic drugs, right?

MR. AZORSKY: Objection to form.

MR. DRAYCOTT: Objection.

A. Yes.

(Ex. BZ, B. Jackson Dep. at 394:6-395:10.)

United States' Response: Objection, this statement is vague because it does not indicate whether the present and former government employees whose testimony is quoted are alleged to have expressed official, as opposed to personal, views regarding the subject matter of their deposition testimony. The United States disputes that Ben Jackson, now or at the time he testified, was employed by the Office of Inspector General, HHS. The United States does not dispute that Mr. Jackson was formerly employed by the OIG. To the extent the above statement purports to state the personal views of the deponents, the United States disputes the relevance of those views in this case. *See United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004) (personal views of agency officials "are irrelevant" when interpreting a regulation). Moreover, any personal view expressed by a federal employee during a deposition may not be construed as the official position of a federal agency. *Id.* ("agency interpretations are relevant only if they are reflected in public documents"). The United States further disputes the materiality of the statement based on the rulings by the District Court construing the term "AWP" pursuant to its plain language and as a matter of law. *See In Re Average Wholesale Price Litig.*, 460 F. Supp. 2d

277, 278 (D. Mass. 2006). The United States does not dispute that the deponents whose testimony is quoted in partial excerpts gave such testimony. The entirety of the testimony referenced is the best evidence of its content.

B. State Testimony

60. Numerous state officials similarly provided testimony that they understood the term AWP to refer to the prices published in the compendia. For example:

> (a) Robert Reid, former Administrator of the Ohio Medicaid Pharmacy Service Unit, testified:
>
> Q. And I assume you've used the term "average wholesale price" with your colleagues in other states-
>
> A. Yes.
>
> Q –right? And from those interactions, is it your view that the term "average wholesale price" is well understood in the industry to mean price published in Red Book, Blue Book, First DataBank?
>
> MS. GEOPPINGER: Object to the form of the question. You can answer.
>
> A. Yes.

(Ex. AK, R. Reid Dep. at 100:13-101:3.)

> (b) M.J. Terrebonne, Louisiana Pharmacy Director, testified:
>
> Q. When you use the term AWP, you mean to refer to prices in the compendia, correct?
>
> MR. FAUCI: Objection, form
>
> THE WITNESS: Yes.
>
> BY MR. TORBORG
>
> Q. And that is how other state pharmacy administrators have used the term as well, correct?
>
> MR. FAUCI: Objection, form.
>
> THE WITNESS: Yes.

(Ex. S, M. Terrebonne Dep. at 79:20-80:6.)

(c) H. Leo Sullivan, former Director of Pharmacy Services for TennCare, testified:

Q. And from your experience in interactions with others in the pharmaceutical industry, including state Medicaid pharmacy administrators, do you believe it is well established in the industry that the term "average wholesale price" refers to published drug prices contained in magazines like Red Book and Blue Book?

MR. DRAYCOTT: Objection.

A. Yes.

(Ex. AJ, H. Sullivan Dep. at 85:10-19.)

Q. It says there AWP is used to refer to the price at which a pharmaceutical firm or wholesaler sells a drug to a retail customer, it then administers it to a patient. Do you see that?

A. Yes.

Q. Do you agree that AWP is referred to, is used to refer to the price at which a pharmaceutical firm or wholesaler sells a drug to a retail customer?

A. No.

MR. DRAYCOTT: Objection.

A. No.

(*Id.* at 87:19-88:09.)

(d) John Young, former State Medicaid Director for Rhode Island, testified:

Q. Is it your understanding that AWP means a nondiscounted list price?

A. In general, yes.

Q. Is it also your understanding that pharmacies purchase drugs at prices that are discounted significantly below AWP?

A. I understand that that possibility exists, which is the reason for the usual and customary provision.

Q. Have you ever understood AWP to be the same thing as the actual acquisition cost for-a pharmacy makes to purchase a drug?

A. No.

Q. Is it your understanding that anyone at Rhode Island Medicaid has understood AWP to be the same thing as actual acquisition costs to pharmacies?

MS. BAUM: Objection.

MS. SMITH: Objection.

WITNESS: Not that I know.

(Ex. CA, J. Young Dep. at 57:20-58:17.)

(e) Sandra Kramer, former Policy Analyst for Michigan Medicaid, testified:

Q. Okay. Did you understand that AWP referred to prices published in pricing compendia?

A. Yes.

(Ex. CB, S. Kramer Dep. at 67:8-10.)

United States' Response: Objection, legal conclusions regarding legislative intent are not resolved as disputed or undisputed factual statements pursuant to Fed. R. Civ. P. 56. Objection, the statement is overly vague in that Abbott failed to specify, either in the first sentence of the above statement or during the depositions quoted above, whether it was using the term "AWP" as used in statutes and regulations or as a reference to a category of information set forth in published compendia. The United States disputes the materiality of the above statement. The United States does not dispute that Robert Reid, M.J. Terrebonne, H. Leo Sullivan, John Young or Sandra Kramer testified as set forth above. Abbott has correctly, but selectively, quoted excerpts from the testimony of those witnesses. The entirety of the testimony referenced is the best evidence of its content. Further responding, the United States does not dispute that compendia publish a category of information referred to as AWPs. All 49 states for which the

United States is seeking damages relied upon one of the major compendia (First Data, Medispan or Redbook) to obtain AWP and/or WAC pricing. (*See* Henderson Decl., Ex. 24 (Declaration of Myers and Stauffer LC at ¶ 24 c.). Forty-nine (49) states used AWP as the primary basis for determining the Estimated Acquisition Cost ("EAC") component to their state's drug reimbursement methodology during the period of 1991 to the present; and forty-two (42) of those states used AWP as the primary basis for determining the EAC component to their state's drug reimbursement methodology for the entire time period of 1991 to present. (*Id*. at ¶ 24 a.). State Medicaid officials have testified that they relied upon the compendia to obtain timely and accurate pricing information. (*See, e.g.*, Lavine Decl. at Ex. USAbt-C, S. Bridges Dep. at 43-44 (Arkansas); Ex. USAbt-F, J. Parker Dep. at 62-64 (Illinois); Ex. USAbt-H, G. Cheloha Dep. at 341 (Nebraska); Ex. USAbt-P, M. Clifford Dep. at 203 (New Hampshire); Ex. USAbt-R, L. Weeks Dep. at 43-44 and 101-104 (North Carolina); Ex. USAbt-V, L. Iverson Dep. at 139 ("My opinion is that we get the AWP from First Data Bank and that that is an accurate AWP. . . That that is the average wholesale price.") (South Dakota); Ex. USAbt-J, A. Rugg Dep. at 357-358 (Vermont); Ex. USAbt-U, A. Hautea-Wimpee Dep. at 105:2-105:8 and 137-138, and Ex. USAbt-T, M. Davis Dep. at 61:2-61:20 Washington)). Further responding, Medicaid officials, including some of the same Medicaid officials whose testimony Abbott cites above, testified that the state understood AWP to be defined according to its plain meaning (*see, e.g.*, Ex. USAbt-C, S. Bridges Dep. at 63-64 (Arkansas)); that they understood AWP to be "an average of wholesale prices for a particular product" (Ex. USAbt-Q, E. Vaccaro Dep. at 70-72 (New Jersey)); that they believed there was a predictable relationship between the published AWPs and actual market prices (*see, e.g.*, Ex. USAbt-H, G. Cheloha Dep. at 341 (Nebraska); Ex. USAbt-O, L. Farrand Dep. at 282-284, and Ex. USAbt-P, M. Clifford Dep. at 203 (New Hampshire); and Ex.

USAbt-J, A. Rugg Dep. at 357-358 (Vermont)); and that they assumed that manufacturers who wished to participate in Medicaid programs would report true and accurate prices to First DataBank (Ex. USAbt-U, A. Hautea-Wimpee Dep. at 358 (Washington)).

61. State Medicaid Officials testified regarding their knowledge of spreads between acquisition cost and published AWPs, including:

(a) H. Leo Sullivan, former Director of Pharmacy Services for TennCare, testified:

Q. Did you believe that you could shave 20, 30 percent off of it and get a reliable number of what pharmacies and physicians actually paid for drugs.

A. Well, it would, it would depend on-I mean, are we talking brand or generic?

Q. Both right now. Would you draw a distinction?

A. Oh, yeah. Yeah. . . . The generic drugs, you know, you could pay AWP minus 80 percent and still the pharmacist make money for some, I assume. But AWP minus 25 might be below cost for a brand name drug for a rural pharmacy that has a very small volume. Okay? So there is, there is a difference between brand and generic. . . . But to say 20-30 percent, use that number, you would have to distinguish between brand and generic.

(Ex. AJ, H. Sullivan Dep. at 100:13-101:18.)

(b) David Campana, Alaska's Director of Pharmacy, provided the following testimony:

Q. Now, we have spoken about benchmark prices. Did you come to an understanding, sir, at any point during this time period, from 1960s right up until 1990, whether the differential between the benchmark price and the actual price being paid by a pharmacy for drugs was greater for generic drugs than it was for branded drugs?

A. Yes, I've come across that information.

Q. What is your understanding of what happens in that area?

MR. BURNHAM: During what time period?

BY MR. MANGI: Q. Let's start with-well, back up. When you say you have come across that information, when did you first become aware of that phenomenon?

A. I don't remember time period.

Q. Would it be fair to say it's a long time ago?

A. Yeah.

MR. HENDERSON: Objection.

BY MR. MANGI: Q. In other words, would you say that's-perhaps bucketed by decades, would it be fair to say that's perhaps sometime in the '60s or the '70s as opposed to the '80s or the '90s?

A. It's hard to say when I became aware of that.

Q. Well, would it be fair to say it was before 1990?

A. Yes.

Q. And what generally did you become aware of, sir?

A. That the net cost to the pharmacy for generics that have been out for a long time was very low compared to the benchmark.

Q. And benchmark that we are talking about here, so the record is clear, is AWP, correct?

A. Correct.

Q. So in other words, at some point prior to 1990, you became aware that when generics come into the market, there is increased competition, correct?

MR. BURNHAM: Objection, foundation.

THE WITNESS: There is increased competition the longer the generic is available.

(Ex. R, D. Campana Dep. at 93:15-95:16.)

* * *

Q. Is it fair to say, sir, that there is, therefore, no predictable relationship between the AWP of a generic drug and the actual price that a pharmacy is paying to purchase that generic drug?

MR. BURNHAM: Objection, form.

MR. HENDERSON: Objection.

THE WITNESS: I have never seen a formula to exactly determine that.

BY MR. MANGI: Q. In other words, you understand that it's just something that's going to vary for generic drugs depending on the extent of competition, correct?

MR. BURNHAM: Objection.

THE WITNESS: Yes.

BY MR. MANGI: Q. And you have understood that going back a number of years. You are not sure when exactly, but certainly since before 1990 you have had that understanding, correct?

A. Yes.

(*Id.* at 98:8-99:7.)

(c) Suzette Bridges, Administrator of the Arkansas Medicaid Prescription Drug Program, provided the following testimony:

Q. And based on what we've seen, you would expect that the discounts available for pharmacies, when purchasing generic drugs, are typically greater than the discounts when purchasing branded drug?

MS. OBEREMBT: Objection.

A. I can only make that assumption based on the survey findings. The survey findings generally show that-and I'd have to look at the survey again, that the variance on brand is not as great on the variance on generics. I mean, that's common knowledge. I'd guess you'd say.

MR. REALE: Let me mark the next one.

A. A common assumption. Excuse me. Let me rephrase that.

(Ex. CC, S. Bridges Dep. at 358:20-359:13.)

(d) Kevin Gorospe, Chief of MediCal Pharmacy Policy provided the following testimony:

Q. This document refers to the August 1989 report from the US Senate which reported that organizations, such as the Department of Veterans Affairs, hospitals and HMOs, are negotiating prices directly with manufacturers at discounts of 41

to 99 percent off the published average wholesale price, correct?

A. That's what it says, yes.

Q. So DHS knew, no later than August of 1991, that certain pharmaceutical purchasers received discounts of up to-from anywhere from 41 to 99 percent off of the published AWP, correct?

MR. PAUL: Objection. Form. No foundation to DHS.

MR. GOBENA: Same objection.

THE WITNESS: I would assume anybody that read the report would have read this passage.

BY MR. COLE:

Q. Anyone who would have read the report would have learned this information at that time, correct?

A. That is correct.

(Ex. CD, K. Gorospe Dep. at 212:16 - 213:17.)

Q. Did you have that understanding also going back to the late nineties, that AWP minus 20 percent is significantly higher than pharmacy acquisition costs for generic drugs?

A. Yes.

Q. Last sentence of that paragraph or that page, I guess, going over to the next page, "The reimbursement of generic drugs will still be significantly above pharmacy's acquisition costs." And then it goes on. Did I read that correctly?

A. Yes.

Q. Do you understand that to-Withdrawn. So was it your understanding to the extent you recall this proposal that the reimbursement rate of AWP minus 20 percent was made knowing that reimbursement on that basis would be significantly higher than acquisition costs for generic drugs?

A. Yes.

(*Id.* at 594:7-595:5.)

(e) Jerry Wells, former Pharmacy Program Manager for Florida Medicaid,

provided the following testimony:

Q. And for innovator multisource products, what was the discount they were able to receive?

A. It was 43.41 percent.

Q. What are innovator multisource products?

A. That is a product whose patent has expired but is still marketed by the original NDA applicant.

Q. Do you have an expectation for what the discounts from AWP would be for noninnovator multisource products?

A. Because those manufacturers and suppliers tend to overstate their AWPs, you can see 80 or 90 percent in some cases.

(Ex. AL, J. Wells Dep. at 206:2-206:15.)

Q. The right side of the graph with the increasing number of discounts all the way up to more than 90 percent off, is that consistent with your understanding of how deeply discounted generic products tend to be in the marketplace?

A. That looks like a more normal distribution curve for discounts.

Q. And when you talk about manufacturers inflating the average wholesale price, would you agree with me that this indicates that virtually all of the average wholesale prices for the generic drugs that are represented in this graph are at least four times greater than the average acquisition cost for those products?

MS. ST. PETER-GRIFFITH: Object to the form.

MS. WALLACE: Objection, form.

THE WITNESS: I can't do the math that quickly, but I would agree that they are higher.

BY MR. COOK:

Q. The outlier would the generic drug that is sold somewhere close to AWP, not the generic drug that's sold for five cents on the dollar, right?

MS. ST. PETER-GRIFFITH: Object to the form.

MS. WALLACE: Objection to form.

THE WITNESS: I would agree.

BY MR. COOK:

Q. And is that consistent with your understanding of the way generic drugs are priced in the marketplace?

A. I think–

MS. ST. PETER-GRIFFITH: Object to the form.

MS. WALLACE: Objection to form.

THE WITNESS: –so.

(*Id.* at 223:17-225:09)

Q. Would that be a better characterization for AWP with respect to generics?

MS. ST. PETER-GRIFFITH: Object to form.

MS. WALLACE: Object to form.

THE WITNESS: I don't know that that article said that. There was a letter from Ven-a-Care that mentioned that AWP was a joke. AWP was a pricing reference point that is a reasonable indicator of approximate cost for brand name drugs. It is no longer a reasonable indicator for generic drugs and I don't know when that diversion occurred. At one point it probably was a reasonable indicator for generic drugs.

BY MR. COOK: Certainly by 1990 it was no longer a reasonable indicator of price for generic drugs, correct?

MS. WALLACE: Object to form.

MS. ST. PETER-GRIFFITH: Object to the form.

MR. BREEN: Object to form.

THE WITNESS: I think that by 1990 that would be a valid statement.

(*Id.* at 339:20-341:02.)

(f) James Parker, Illinois Medicaid Deputy Administrator, provided the following testimony:

Q. And the reason that this budget initiative was proposed was because AWP had become virtually meaningless as a real number, particularly for multi source drugs, correct?

A. That is correct.

(Ex. CE, J. Parker Dep. at 182:1-5.)

(g) M.J. Terrebonne, Louisiana Pharmacy Director, provided the following testimony:

Q. And on page 172 Mr. Torborg asked you if you knew that there was a wider variation for discounts from AWP for generic drugs, and on line 14 of page 172 you say "Yes." Sitting here today as a representative for the State of Louisiana, do you agree with and adopt this–your prior testimony on this point?

A. Yes, based on the survey.

Q. The survey from 1999?

A. Correct.

Q. Please turn to page 47 of this document, page 185 of your testimony. Let me know when you get there.

A. (Witness examines documents.) I'm there.

Q. On line 9 of page 185, Mr. Torborg asks you: As far as you can recall, you've always been aware of the joke, quote, "AWP equals ain't what's paid," unquote, and your response on line 13 is "Pretty much, yes. It's a running joke," unquote.

Sitting here today as the representative for the State of Louisiana, is it fair to say that the joke "AWP equals ain't what's paid" is a running joke that's been known for some time for the State of Louisiana?

MR. FAUCI: Object to the form.

THE WITNESS: I wouldn't say just for the State of Louisiana. It's just a common statement.

(Ex. S, M. Terrebonne Dep. at 48:02-49:09.)

(h) Sandra Kramer, Former Policy Analyst for Michigan Medicaid, provided the following testimony:

Q. Okay. The next paragraph you say: "As an example, I have attached the

> direct (or acquisition cost) and AWP for several new products from a major generic company. The price differentials are enormous with AWP ranging from 13 percent to 500 percent above acquisition cost!!!"
>
> With the three exclamations, were you also trying to get his attention?
>
> MR. HENDERSON: Objection.
>
> A. I think it speaks for itself.
>
> BY MR. GABEL:
>
> Q. Okay. Fair enough. You state: "The price differentials are enormous–" well, actually, strike that. It's fair to say that as early as 1992 you realized that in some instances AWPs were upwards of 500 percent above acquisition costs?
>
> A. For the generic.
>
> Q. For the generic specifically?
>
> A. That's what I'm referring to here.

(Ex. CB, S. Kramer Dep. at 93:5-94:2.)

United States' Response: The United States disputes the materiality of the above statement. The United States does not dispute that the individuals whose testimony is cited, testified as set forth above. Abbott has correctly, but selectively, quoted excerpts from the testimony of those witnesses. The entirety of the testimony referenced is the best evidence of its contents. Not only is the testimony Abbott references selectively cited, Abbott chose only to cite to portions of transcripts of a handful of Medicaid officials whose testimony supported Abbott's position. The United States does not dispute that pharmacies could buy drugs at a discount from AWP, nor does the United States dispute that the difference between AWP and Actual Acquisition Cost ("AAC") could, in some cases, be larger for generic drugs than for brand drugs. The United States disputes, however, the relevancy of the testimony to Abbott's liability under the FCA. The testimony does not mention Abbott or refer to any of the Subject Drugs, and the

"spreads" referred to in the testimony are much smaller than most of those created by Abbott for the Subject Drugs. Further responding, Medicaid officials, including some of the same Medicaid officials whose testimony Abbott cites above, testified that:

(a) Although they were generally aware that AAC could be lower than AWP, they were not aware of the large spreads at issue in this case. (*See, e.g.*, Lavine Decl. at Ex. USAbt-C, S. Bridges Dep. at 251:18-252:15 (Arkansas); Ex. USAbt-E, J. Dubberly Dep. at 372:3-373:13 (Georgia); Ex. USAbt-G, J. Fine Dep. at 48-50 (Maryland); Ex. USAbt-W, S. Kramer Dep. at 108:3-109:7 and 115:20-116:5 (Michigan); Ex. USAbt-N, S. McCann Dep. at 49:7-50:22 (Missouri); Ex. USAbt-P, M. Clifford Dep. at 243:11-244:11 (New Hampshire); Ex. USAbt-R, L. Weeks Dep. at 119:18-120:22, 123:19-124:21 and 386:6-386:13 (North Carolina); Ex. USAbt-X, B. Ridout Dep. at 47:14-48:9, 59:22-61:1, 72:13-75:5, 102:1-102:16, 166:18-169:15 and 198:15-198:20 (North Carolina); Ex. USAbt-Y, J. Anderson Dep. at 229:17-230:8 (Oregon); Ex. USAbt-AA , J. Young Dep. at 266:1-266:15 (Rhode Island); and Ex. USAbt-U, A. Hautea- Wimpee Dep. at 139:1-141:4 and 157:21-158:14 (Washington)).

(b) States attempted to determine EAC in accordance with federal regulations defining EAC as "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of the drug must frequently purchased by providers." Fed. Reg. Vol. 52, No. 147 § 447.301 (1987). (*See, e.g.*, Lavine Decl. at Ex. USAbt-K, D. Campana Dep. at 266-268 (Alaska); Ex. USAbt-C, S. Bridges Dep. at 29-31 (Arkansas); Ex. USAbt-D, A. Chapman Dep. at 307:4-310:16

(Colorado); Ex. USAbt-E, J. Dubberly Dep. at 39-42 (Georgia); Ex. USAbt-F, J. Parker Dep. at 32-34 (Illinois); Ex. USAbt-H, G. Cheloha Dep. at 350-353 (Nebraska); Ex. USAbt-P, M. Clifford Dep. at 209-210 (New Hampshire); Ex. USAbt-Q, E. Vaccaro Dep. at 35 (New Jersey); Ex. USAbt-R, L. Weeks Dep. at 32-34 (North Carolina); Ex. USAbt-AA, J. Young Dep. at 54 (Rhode Island); Ex. USAbt-V, L. Iverson Dep. at 162 (South Dakota); Ex. USAbt-J, A. Rugg Dep. at 366 (Vermont); Ex. USAbt-S, B. Tomlinson Dep. at 31-33 (Virginia); Ex. USAbt-Z, R. Homar Dep. at 390 (Wyoming); and Ex. USAbt-U, A. Hautea-Wimpee Dep. at 69:9-71:22 (Washington)).

(c) State Medicaid officials never told manufacturers that they understood or approved of manufacturers reporting inflated AWPs. (*See, e.g.*, Lavine Decl. at Ex. USAbt-L, K. Gorospe Dep. of Dec. 3, 2008 at 293-295 (California); Ex. USAbt-B, C. Denemark Dep. at 485:1-486:13 (Delaware); Ex. USAbt- E, J. Dubberly Dep. at 76-77 and 355-358 (Georgia); Ex. USAbt-I, R. Stevens Dep. at 322-323 (New Mexico); Ex. USAbt-T, M. Davis Dep. at 63:12-66:21, 68:8-70:12, and Ex. USAbt-U, A. Hautea-Wimpee Dep. at 141:17-144:10, 147:4-148:12, 155:18-161:13 (Washington)).

IV. THE GOVERNMENT'S MOTIONS TO EXTEND THE SEAL

62. On August 18, 1995, the United States filed an *ex parte* Memorandum in Support of the United States' Ex Parte Motion for an Extension of Time, seeking a 90 day extension to the under seal period. In the memorandum, the United States wrote that "Congress recognized that the Government would frequently require additional time in which to make an informed decision on whether to assume control over the action, as required by the Act," citing S. Rep. No. 99-345 at 25, *as reprinted* in 1986 U.S.C.C.A.N. 5266, 5290. (Ex. CF at 3 (ABT008-211-15).) Several subsequent motions to extend the seal "refer[red] the Court to this previously submitted memorandum" for the "Legal Authority supporting the proposed extension." (Ex. CG at 2 n.1 (ABT008-0199-205) (Nov. 1995); Ex. CH at 2 n.1 (ABT008-0192-0195) (May 1996); Ex. CI at 3 n.1 (ABT008-0180-83)

(Jul. 1996); Ex. CJ at 2 n.1 (ABT008-0165-68) (Nov. 1996); Ex. CK at 3 n.1 (ABT008-0154-56) (Mar. 1997); Ex. CL at 2 n.1 (ABT008-0339-42) (Oct. 1997); Ex. CM at 2 n.1 (ABT008-1118-20) (Jan. 1998); Ex. CN at 1 n.1 (ABT008-1061-65) (Nov. 1998); Ex. CO at 1 n.1 (ABT008-1034-36) (Apr. 1999); Ex. CP at 1 n.1 (ABT008-1020-1023) (Aug. 1999); Ex. CQ at 1 n.1 (ABT008-1008-10) (Nov. 1999); Ex. CR at 1 n.1 (ABT008-1629-33) (Mar. 2000); Ex. CS at 1 n.1 (ABT008-1611-15) (Jul. 2000); Ex. CT at 1 n.1 (ABT008-1570-76) (Jan. 2001); Ex. CU at 1 n.1 (Jul. 2001); Ex. CV at 1 n.1 (ABT008-1544-49 (Oct. 2001); Ex. CW at 1 n.1 (ABT008-1509-14) (Feb. 2002); Ex. CX at 1 n.1 (ABT008-1499-05) (Jun. 2002); Ex. CY at 1 n.1 (ABT008-1485-91) (Oct. 2002).)

United States' Response: The United States disputes the materiality of the above statement but not the facts stated therein.

63. On August 18, 1995, the United States filed an *ex parte* Motion for Extension of Seal on Qui Tam Complaint and Related Filings and for Extension of the Government's Evaluatory Period. In the motion, the United States wrote that "a complete investigation is needed in order for the government to make an informed decision whether to intervene and take over this action pursuant to 31 U.S.C. § 3730(b)(4)." (Ex. CZ at 1 (ABT008-0217-18).) The accompanying memorandum in support indicated a need to "keep the complaint in this action under seal pending the Government's completion of the additional investigation and analysis necessary in this complex case." (Ex. CF at 3 (ABT008-211-15).) Subsequent motions to extend the seal filed between November 1995 and November 1996 likewise indicated that a "complete investigation" was needed before the United States could make its intervention decision, but that the investigation had not been completed. (Ex. CG at 2 (ABT008-0199-205) (Nov. 1995); Ex. CH at 2 (ABT008-0192-0195) (May 1996); Ex. CI at 2 (ABT008-0180-83) (Jul. 1996); Ex. CJ at 2 (ABT008-0165-68) (Nov. 1996).)

United States' Response: The United States disputes the materiality of the above statement but not the facts stated therein. The United States disputes any implication that filing the extension application *ex parte* was improper. Applications to extend the seal in FCA cases are filed *ex parte* pursuant to the FCA. *See* 31 U.S.C. § 3730(b)(3). Accordingly, the *ex parte* filing was appropriate and lawful.

64. On March 22, 1996, Assistant United States Attorney Mark A. Lavine executed a declaration which was attached to the United States' *ex parte* Motion for Extension of Seal on *Qui Tam* Complaint filed in May 1996. In that declaration, Mr. Lavine stated that "on January 23, 1996, Attorney General Janet Reno, at our request, authorized the service of Civil Investigative Demands [on] Abbott Laboratories." He further stated that "the CIDs demanded the production of several different categories of documents relevant to

> the government's investigation of the merits of the *qui tam* suit, including all documents that discuss or comment upon the policies that Abbott followed in setting of [its] direct prices, wholesale acquisition cost, or average wholesale price for several specific drugs that are reimbursed by the Medicare program." Mr. Lavine stated that his office had "received 6 boxes of documents from Abbott" and "[i]n addition, Abbott has informed us that an additional 2700 boxes of documents are available for review at their facilities." (Ex. DA at 3-4 (ABT008-0187-90).) Declarations filed with subsequent *ex parte* motions to extend the seal likewise referenced these CID requests:
>
> (a) On November 21, 1996, Mr. Lavine filed a declaration stating that "the government has continued to review documents obtained by Civil Investigative Demand from Abbott Laboratories." (Ex. DB at 3 (ABT008-0160-63));
> (b) On March 24, 1997, Mr. Lavine filed a declaration stating that "the government has continued to review documents obtained by Civil Investigative Demand from Abbott Laboratories." (Ex. DC at 4 (ABT0080147-52));

United States' Response: The United States disputes the materiality of the above statement. Applications to extend the seal in FCA cases are filed *ex parte* pursuant to the FCA. *See* 31 U.S.C. § 3730(b)(3). Notwithstanding the seal in place on this case, Abbott was aware of the investigation by January 1996, and received HHS-OIG subpoenas in 1997 and 2000. Indeed, Abbott lodged lengthy objections to the 2000 subpoena and ultimately ignored it, undermining the government's effort to conduct the investigation. (*See* Lavine Decl. at Ex. 64 (August 28, 2000 letter from Christopher Cook to Mark Lavine and Linda Hiller)). Abbott's counsel met with the government several times during the investigation to discuss the allegations. (*See, e.g.*, Lavine Decl. at Ex. 65 (November 3, 1999 letter from T. Reed Stephens to Daniel Reidy, referencing an October 27, 1999 presentation by the government to Abbott and its counsel)). In addition, Abbott was a member of a coalition of defendants who sought to discourage the United States from intervening in the matter. (*See* Lavine Decl. at Ex. 61 (March 17, 2000 Memorandum from Defendants Arguing Against Intervention) and Ex. 62, (September 1, 2000 letter from Daniel Reidy on behalf of Abbott joining in the Defendants' March 17, 2000 Memorandum)). Abbott had communications with the government about the subpoena,

settlement and potential intervention from 1996 through the government's intervention in this matter.

65. On May 7, 1997, the United States filed an *ex parte* Motion for Partial Lifting of the Seal to Disclose to State Attorneys General and Memorandum of Law. In that document, the United States stated that "[i]t is in the interest of justice that the Attorney General of each State defrauded of their respective portion of the Medicaid payments paid for the specified infusion and injectable drugs be put on notice of these proceedings in order for the state to be able to identify the amount of the losses of that state and to advocate the recovery of that state's losses from the fraud scheme set forth in the Amended Complaint." (Ex. DD at 3 (ABT008-0659-64).)

United States' Response: The United States disputes the materiality of the above statement. Applications to extend the seal in FCA cases are filed *ex parte* pursuant to the FCA. *See* 31 U.S.C. § 3730(b)(3). Further, Abbott was aware of the investigation by January 1996, and received HHS-OIG subpoenas in 1997 and 2000. (*See, e.g.*, Lavine Decl. at Ex. 61-66). Indeed, Abbott lodged lengthy objections to the 2000 subpoena and ultimately ignored it, undermining the government's effort to conduct the investigation. (*See* Lavine Decl. at Ex. 64 (August 28, 2000 letter from Christopher Cook to Mark Lavine and Linda Hiller)). Abbott's counsel met with the government several times during the investigation to discuss the allegations. (*See, e.g.*, Lavine Decl. at Ex. 65 (Nov. 3, 1999 letter from T. Reed Stephens to Daniel Reidy, referencing an October 27, 1999 presentation by the government to Abbott and its counsel)). In addition, Abbott was a member of a coalition of defendants who sought to discourage the United States from intervening in the matter. (*See* Lavine Decl. at Ex. 61 (March 17, 2000 Memorandum from Defendants Arguing Against Intervention) and Ex. 62 (September 1, 2000 letter from Daniel Reidy on behalf of Abbott joining in the Defendants' March 17, 2000 Memorandum)). Abbott had communications with the government about the subpoena, settlement and potential intervention from 1996 through the government's intervention in this matter.

66. On May 16, 1997, the United States filed an *ex parte* Memorandum in Support of Its Unopposed Request for a Ninety Day Extension of Time to Elect Whether to Intervene. In that memorandum, the United States indicated that the Relator alleged "losses across the board by every states' Medicaid program" and that "[w]hile the Government does not propose the lengthy extension necessary to contact every states' Office of Attorney General, the Government believes that ninety days is sufficient to permit meaningful contacts with the knowledgeable authorities in enough states to allow a meaningful assessment of the Medicaid fraud allegations." The United States also indicated that it had already met with state Medicaid officials from New Jersey, and was preparing to meet Florida state Medicaid officials in the coming days. (Ex. DE at 4 (ABT008-642-46).)

United States' Response: The United States disputes the materiality of the above statement. Applications to extend the seal in FCA cases are filed *ex parte* pursuant to the FCA. *See* 31 U.S.C. § 3730(b)(3). The *ex parte* filing was appropriate and lawful. Further, Abbott was aware of the investigation by January 1996, and received HHS-OIG subpoenas in 1997 and 2000. (*See, e.g.*, Lavine Decl. at Ex. 61-66). Indeed, Abbott lodged lengthy objections to the 2000 subpoena and ultimately ignored it, undermining the government's effort to conduct the investigation. (*See* Lavine Decl. at Ex. 64 (August 28, 2000 letter from Christopher Cook to Mark Lavine and Linda Hiller)). Abbott's counsel met with the government several times during the investigation to discuss the allegations. (*See, e.g.*, Lavine Decl. at Ex. 65 (November 3, 1999 letter from T. Reed Stephens to Daniel Reidy, referencing an October 27, 1999 presentation by the government to Abbott and its counsel)). In addition, Abbott was a member of a coalition of defendants who sought to discourage the United States from intervening in the matter. (*See, e.g.*, Lavine Decl. at Ex. 61 (March 17, 2000 Memorandum from Defendants Arguing Against Intervention) and Ex. 62 (September 1, 2000 letter from Daniel Reidy on behalf of Abbott joining in the Defendants' March 17, 2000 Memorandum)). Abbott had communications with the government about the subpoena, settlement and potential intervention from 1996 through the government's intervention in this matter.

67. On August 20, 1997, the United States filed an *ex parte* Status Report indicating that "[s]ubstantial activity has occurred since the United States last brought this matter before the Court," including "many meetings and conferences [that] have been held with representatives of the Medicaid programs of the states of Florida, Texas, and New Jersey," along with "preliminary discussions" with "the Medicaid programs of other states as well." The United States stated that the "meetings have been productive, particularly with regard to enlisting the aid of each state in searching for relevant information and data." The United States also reported receiving from the state programs "documentary evidence" and "computer data regarding the billings for many of the drugs at issue," and indicated that it was preparing "Inspector General subpoenas for service upon each of the named defendants." (Ex. DF at 1-3 (ABT008-354-58).)

United States' Response: The United States disputes the materiality of the above statement. Applications to extend the seal in FCA cases are filed *ex parte* pursuant to the FCA. *See* 31 U.S.C. § 3730(b)(3). The *ex parte* filing was appropriate and lawful. Further, Abbott was aware of the investigation by January 1996, and received HHS-OIG subpoenas in 1997 and 2000. (*See, e.g.*, Lavine Decl. at Ex. 61-66). Indeed, Abbott lodged lengthy objections to the 2000 subpoena and ultimately ignored it, undermining the government's effort to conduct the investigation. (*See, e.g.*, Lavine Decl. at Ex. 64) (August 28, 2000 from Christopher Cook to Mark Lavine and Linda Hiller)). Abbott's counsel met with the government several times during the investigation to discuss the allegations. (*See, e.g.*, Lavine Decl. at Ex. 65) (November 3, 1999 letter from T. Reed Stephens to Daniel Reidy, referencing an October 27, 1999 presentation by the government to Abbott and its counsel)). In addition, Abbott was a member of a coalition of defendants who sought to discourage the United States from intervening in the matter. (*See, e.g.*, Lavine Decl. at Ex. 61) (March 17, 2000 Memorandum from Defendants Arguing Against Intervention) and Ex. 62 (September 1, 2000 letter from Daniel Reidy on behalf of Abbott joining in the Defendants' March 17, 2000 Memorandum)). Abbott had communications with the government about the subpoena, settlement and potential intervention from 1996 through the government's intervention in this matter.

68. On October 17, 1997, the United States filed an *ex parte* Motion for Extension of the Seal on Qui Tam Complaint Through January 15, 1998. In that motion, the United States sought to extend the seal by noting that "[e]ach defendant had indicated that, although they will be able to commence production on or before the October 31 return date, an extension of time to complete the production of documents will be necessary" and that it "expects to begin receiving responsive documents beginning on the subpoena return date and continuing throughout the remainder of the period covered by the requested extension." (Ex. CL at 2 (ABT008-339-41).)

United States' Response: The United States disputes the materiality of the above statement. Applications to extend the seal in FCA cases are filed *ex parte* pursuant to the FCA. *See* 31 U.S.C. § 3730(b)(3). The *ex parte* filing was appropriate and lawful. Further, Abbott was aware of the investigation by January 1996, and received HHS-OIG subpoenas in 1997 and 2000. (*See, e.g.*, Lavine Decl. at Ex. 61-66). Indeed, Abbott lodged lengthy objections to the 2000 subpoena and ultimately ignored it, undermining the government's effort to conduct the investigation. (*See, e.g.*, Lavine Decl. at Ex. 64) (August 28, 2000 from Christopher Cook to Mark Lavine and Linda Hiller)). Abbott's counsel met with the government several times during the investigation to discuss the allegations. (*See, e.g.*, Lavine Decl. at Ex. 65) (November 3, 1999 letter from T. Reed Stephens to Daniel Reidy, referencing an October 27, 1999 presentation by the government to Abbott and its counsel)). In addition, Abbott was a member of a coalition of defendants who sought to discourage the United States from intervening in the matter. (*See, e.g.*, Lavine Decl. at Ex. 61) (March 17, 2000 Memorandum from Defendants Arguing Against Intervention) and Ex. 62 (September 1, 2000 letter from Daniel Reidy on behalf of Abbott joining in the Defendants' March 17, 2000 Memorandum)). Abbott had communications with the government about the subpoena, settlement and potential intervention from 1996 through the government's intervention in this matter.

69. "In March 1998, the United States and relator came before the Court to request additional time to investigate this matter and pursue settlement negotiations," and that "[i]n response, the Court extended the time to make an intervention election until November

23, 1998." (Ex. DG at 2-3 (ABT008-1066-76).)

United States' Response: The United States disputes the materiality of the above statement but does not dispute that is a partial excerpt from the declaration that is Abbott Exhibit DG.

70. On November 17, 1998, the United States filed an *ex parte* Application for Extension of Time to Elect Whether to Intervene in *Qui Tam* Action. In that application, the United States described its actions in the case since its March 1998 extension of the seal, including:

- that "twenty-four defendants and two other subpoenaed non-parties have continued to provide documents over the course of the past several months";
- that "[c]ounsel for the United States has pressed defendants to state all responsive documents have been produced yet defendants continue to produce additional documents";
- that "[t]he United States has also incurred considerable expense creating an electronic database for storage and review of the thousands of documents"; and
- that "the United States has pursued a non-stop agenda of meetings and telephone conferences with numerous parties" including "defense counsel," "state Medicaid entities," and "representatives of the 47 state Medicaid Fraud Control Units."

The motion then stated that "the first sixty days of the requested extension will permit counsel for the United States to have initial substantive meetings with the remaining 14 defendants and continue to meet with counsel for the first ten. The final 90 days of the requested extension will be devoted to completing any settlement negotiations." It indicated that "the five month extension will allow the United States and the State representatives to complete its investigation." (Ex. CN at 2-3 (ABT008-1061-64).)

United States' Response: The United States disputes the materiality of the above statement. Applications to extend the seal in FCA cases are filed *ex parte* pursuant to the FCA. *See* 31 U.S.C. § 3730(b)(3). The *ex parte* filing was appropriate and lawful. Further, Abbott was aware of the investigation by January 1996 and received HHS-OIG subpoenas in 1997 and 2000. (*See, e.g.*, Lavine Decl. at Ex. 61-66). Indeed, Abbott lodged lengthy objections to the 2000 subpoena and ultimately ignored it, undermining the government's effort to conduct the

investigation. (*See, e.g.*, Lavine Decl. at Ex. 64) (August 28, 2000 from Christopher Cook to Mark Lavine and Linda Hiller)). Abbott's counsel met with the government several times during the investigation to discuss the allegations. (*See, e.g.*, Lavine Decl. at Ex. 65) (November 3, 1999 letter from T. Reed Stephens to Daniel Reidy, referencing an October 27, 1999 presentation by the government to Abbott and its counsel)). In addition, Abbott was a member of a coalition of defendants who sought to discourage the United States from intervening in the matter. (*See, e.g.*, Lavine Decl. at Ex. 61) (March 17, 2000 Memorandum from Defendants Arguing Against Intervention) and Ex. 62 (September 1, 2000 letter from Daniel Reidy on behalf of Abbott joining in the Defendants' March 17, 2000 Memorandum)). Abbott had communications with the government about the subpoena, settlement and potential intervention from 1996 through the government's intervention in this matter.

71. On November 17, 1998, Department of Justice Attorney T. Reed Stephens filed a Declaration in Support of the United States' Unopposed Application for Extension of Time to Elect Whether to Intervene in *Qui Tam* Action, which provided additional details about the United States' pre-unsealing activities, including:

- that "the Department of Health and Human Services Office of Inspector General" had served subpoenas upon "the Hearst Corporation (controlling entity for First DataBank and Medi-Span) and Medical Economics (controlling entity for the RedBook), the two entities that the defendants utilize to publish the allegedly false prices to the state and federal governments";
- that the United States had "shared hundreds of pages of documents with the NAMFCU members [the National Association of Medicaid Fraud Control Unit] Directors who have responsibility for assessing Medicaid fraud allegations affecting their respective states";
- that the "United States entered into an informal working relationship with the Executive Committee of NAMFCU in order to facilitate the identification of witnesses and evidence relevant to the allegations"; and
- that "the United States and Relator and its counsel met with representatives of the state of Illinois in Chicago, Illinois to obtain additional assistance in gathering evidence regarding the *qui tam* matter."

(Ex. DG at 3-5, 10 (ABT008-1066-76).)

United States' Response: The United States disputes the materiality of the above statement, but does not dispute that the affidavit contains the partial excerpts described in the statement.

72. On April 22, 1999, the United States filed an *ex parte* Application for Extension of Time to Elect Whether to Intervene in *Qui Tam* Action. Abbott was provided only an incomplete version of the application. The filing indicated that the seal should be extended for reasons to "permit counsel for the United States to [] continue its witness interviews" and "continue its current settlement negotiations with defendants." (Ex. CO at 2 (ABT008-1034- 36).) An attached Declaration stated that "[c]ounsel for the United States has conducted over a dozen additional witness interviews across the country" and that "[t]he United States has also committed substantial financial resources to creating electronic document storage and review databases for the tens of thousands of pages of documents produced by the defendants pursuant to the subpoenas." (Ex. DH at 3 (ABT008-1038-43).) Several subsequent motions to extend the seal, filed over the course of the next several years, likewise sought extensions to "permit counsel for the United States to":

- "continue its witness interviews," "depositions," or "taking of sworn statements from cooperating witnesses" (Ex. CP at 3 (ABT008-1020-24) (Aug. 1999); Ex. CR at 4 (ABT008-1629-34] (Mar. 2000); Ex. CT at 4 (ABT008-1570-76] (Jan. 2001); Ex. DI at 4 (ABT008-1562-68] (Apr. 2001); Ex. CU at 4 (DE-0114] (Jul. 2001); Ex. CV at 4 (ABT008-1544-49] (Oct. 2001); Ex. CW at 4 (ABT-1509-14] (Feb. 2002); Ex. CX at 4 (ABT-1499-1505] (Jun. 2002); Ex. CY at 5 (ABT-1485-92] (Oct. 2002);

- "continue its current settlement negotiations with defendants" (Ex. CP at 3 (ABT008-1020-24] (Aug. 1999); Ex. DJ at 4 (ABT008-1012-16] (Nov. 1999); Ex. CR at 4 (ABT008-1629-34] (Mar. 2000); Ex. CS at 4 (ABT008-1611-16) (Jul. 2000); Ex. CT at 4 (ABT008-1570-76) (Jan. 2001); Ex. DI at 4 (ABT008-1562-68) (Apr. 2001); Ex. CU at 4 (DE-0114) (Jul. 2001); Ex. CV at 4 (ABT008-1544-49) (Oct. 2001); Ex. CW at 4 (ABT-1509-14) (Feb. 2002); Ex. CX at 4 (ABT-1499-1505) (Jun. 2002); Ex. CY at 5 (ABT-1485-92) (Oct. 2002);

- "push for additional compliance with the agency subpoenas served on defendants" or "other witnesses" (Ex. CP at 3 (ABT008-1020-24) (Aug. 1999); Ex. CR at 4 (ABT008-1629-34) (Mar. 2000); Ex. CS at 4 (ABT008-1611-16) (Jul. 2000); Ex. CT at 4 (ABT008-1570-76) (Jan. 2001); Ex. DI at 4 (ABT008-1562-68) (Apr. 2001); Ex. CU at 4 (DE-0114) (Jul. 2001); and

- "analyze the additional documents that were produced pursuant to subpoenas on

the defendants and witnesses" (Ex. CS at 4 (ABT008-1611-16) (Jul. 2000); Ex. CT at 4 (ABT008-1570-76) (Jan. 2001); Ex. DI at 4 (ABT008-1562-68) (Apr. 2001); Ex. CU at 4 (DE-0114) (Jul. 2001); Ex. CV at 4 (ABT008-1544-49) (Oct. 2001); Ex. CW at 4 (ABT-1509-14) (Feb. 2002); Ex. CX at 4 (ABT-1499-1505) (Jun. 2002); Ex. CY at 5 (ABT-1485-92) (Oct. 2002).

United States' Response: The United States disputes the materiality of the above statement. Applications to extend the seal in FCA cases are filed *ex parte* pursuant to the FCA. *See* 31 U.S.C. § 3730(b)(3). The *ex parte* filing was appropriate and lawful. Further, Abbott was aware of the investigation by January 1996, and received HHS-OIG subpoenas in 1997 and 2000. Indeed, Abbott lodged lengthy objections to the 2000 subpoena and ultimately ignored it, undermining the government's effort to conduct the investigation. (*See, e.g.*, Lavine Decl. at Ex. 64) (August 28, 2000 from Christopher Cook to Mark Lavine and Linda Hiller)). Abbott's counsel met with the government several times during the investigation to discuss the allegations. (*See, e.g.*, Lavine Decl. at Ex. 65) (November 3, 1999 letter from T. Reed Stephens to Daniel Reidy, referencing an October 27, 1999 presentation by the government to Abbott and its counsel)). In addition, Abbott was a member of a coalition of defendants who sought to discourage the United States from intervening in the matter. (*See, e.g.*, Lavine Decl. at Ex. 61) (March 17, 2000 Memorandum from Defendants Arguing Against Intervention) and Ex. 62 (September 1, 2000 letter from Daniel Reidy on behalf of Abbott joining in the Defendants' March 17, 2000 Memorandum)). Abbott had communications with the government about the subpoena, settlement and potential intervention from 1996 through the government's intervention in this matter.

73. On March 23, 2000, the United filed an *ex parte* Unopposed Application for Extension of Time to Elect Whether to Intervene in *Qui Tam* Action. It provided that "the United States has continued to diligently investigate the allegations set forth in the relator's Second Amended Complaint and aggressively pursue settlement discussions with a large number of the defendants." (Ex. CR at 2 (ABT008-1630).)

United States' Response: The United States disputes the materiality of the above statement. Applications to extend the seal in FCA cases are filed *ex parte* pursuant to the FCA. *See* 31 U.S.C. § 3730(b)(3). The *ex parte* filing was appropriate and lawful. Further, Abbott was aware of the investigation by January 1996, and received HHS-OIG subpoenas in 1997 and 2000. Indeed, Abbott lodged lengthy objections to the 2000 subpoena and ultimately ignored it, undermining the government's effort to conduct the investigation. (*See, e.g.*, Lavine Decl. at Ex. 64) (August 28, 2000 from Christopher Cook to Mark Lavine and Linda Hiller)). Abbott's counsel met with the government several times during the investigation to discuss the allegations. (*See, e.g.*, Lavine Decl. at Ex. 65) (November 3, 1999 letter from T. Reed Stephens to Daniel Reidy, referencing an October 27, 1999 presentation by the government to Abbott and its counsel)). In addition, Abbott was a member of a coalition of defendants who sought to discourage the United States from intervening in the matter. (*See, e.g.*, Lavine Decl. at Ex. 61) (March 17, 2000 Memorandum from Defendants Arguing Against Intervention) and Ex. 62 (September 1, 2000 letter from Daniel Reidy on behalf of Abbott joining in the Defendants' March 17, 2000 Memorandum)). Abbott had communications with the government about the subpoena, settlement and potential intervention from 1996 through the government's intervention in this matter.

74. On July 21, 2000, the United States filed an *ex parte* Application for Extension of Time to Elect Whether to Intervene in *Qui Tam* Action. In that motion, the United States noted that a "96-page memorandum of law prepared by the Relators was recently provided to many of the defendants as an additional inducement to settle the case" and that United States' "goal" was "pushing through as many settlements as possible prior to commencing litigation in this matter." (Ex. CS at 3-4 (ABT008-1611-16).)

United States' Response: The United States disputes the materiality of the above statement. Applications to extend the seal in FCA cases are filed *ex parte* pursuant to the FCA. *See* 31 U.S.C. § 3730(b)(3). The *ex parte* filing was appropriate and lawful. Further, Abbott was

aware of the investigation by January 1996, and received HHS-OIG subpoenas in 1997 and 2000. Indeed, Abbott lodged lengthy objections to the 2000 subpoena and ultimately ignored it, undermining the government's effort to conduct the investigation. (*See, e.g.*, Lavine Decl. at Ex. 64) (August 28, 2000 from Christopher Cook to Mark Lavine and Linda Hiller)). Abbott's counsel met with the government several times during the investigation to discuss the allegations. (*See, e.g.*, Lavine Decl. at Ex. 65) (November 3, 1999 letter from T. Reed Stephens to Daniel Reidy, referencing an October 27, 1999 presentation by the government to Abbott and its counsel)). In addition, Abbott was a member of a coalition of defendants who sought to discourage the United States from intervening in the matter. (*See, e.g.*, Lavine Decl. at Ex. 61) (March 17, 2000 Memorandum from Defendants Arguing Against Intervention) and Ex. 62 (September 1, 2000 letter from Daniel Reidy on behalf of Abbott joining in the Defendants' March 17, 2000 Memorandum)). Abbott had communications with the government about the subpoena, settlement and potential intervention from 1996 through the government's intervention in this matter.

75. On October 26, 2001, the United States filed an *ex parte* Application for Extension of Time to Elect Whether to Intervene in *Qui Tam* Action. In that motion, the United States indicated that it was "coordinating with" the Attorneys General of Texas, Florida, and California "to avoid following duplicative areas of discovery." (Ex. CV at 3 (ABT008-1544-49).) Subsequent motions also mentioned coordination to avoid "duplicative areas of discovery," including meetings of state and federal investigators designed to help coordinate and focus the efforts of the various parties." (Ex. CX at 4 (ABT-1499-1505); Ex. CY at 4 (ABT008-1485-90).)

United States' Response: The United States disputes the materiality of the above statement. Applications to extend the seal in FCA cases are filed *ex parte* pursuant to the FCA. *See* 31 U.S.C. § 3730(b)(3). The *ex parte* filing was appropriate and lawful. Further, Abbott was aware of the investigation by January 1996, and received HHS-OIG subpoenas in 1997 and 2000. Indeed, Abbott lodged lengthy objections to the 2000 subpoena and ultimately ignored it,

undermining the government's effort to conduct the investigation. (*See, e.g.*, Lavine Decl. at Ex. 64) (August 28, 2000 from Christopher Cook to Mark Lavine and Linda Hiller)). Abbott's counsel met with the government several times during the investigation to discuss the allegations. (*See, e.g.*, Lavine Decl. at Ex. 65) (November 3, 1999 letter from T. Reed Stephens to Daniel Reidy, referencing an October 27, 1999 presentation by the government to Abbott and its counsel)). In addition, Abbott was a member of a coalition of defendants who sought to discourage the United States from intervening in the matter. (*See, e.g.*, Lavine Decl. at Ex. 61) (March 17, 2000 Memorandum from Defendants Arguing Against Intervention) and Ex. 62 (September 1, 2000 letter from Daniel Reidy on behalf of Abbott joining in the Defendants' March 17, 2000 Memorandum)). Abbott had communications with the government about the subpoena, settlement and potential intervention from 1996 through the government's intervention in this matter. In addition, by this time Abbott had received letters from both the Department of Justice (1999) and a member of Congress (2000) accusing it of committing fraud.

76. On October 22, 2002, the United States filed an *ex parte* Application for Extension of Time to Elect Whether to Intervene in *Qui Tam* Action. In that application, the United States described "[a] project which has taken considerable effort has also been ongoing with respect to efforts to create a database of scanned documents" with "[t]he goal of the project . . . to make all of the scanned documents available in a secure fashion over the internet to all attorneys and investigators working on this case, both state and federal." (Ex. CY at 4 (ABT008-1485-90).)

United States' Response: The United States disputes the materiality of the above statement. Applications to extend the seal in FCA cases are filed *ex parte* pursuant to the FCA. *See* 31 U.S.C. § 3730(b)(3). The *ex parte* filing was appropriate and lawful. Further, Abbott was aware of the investigation by January 1996, and received HHS-OIG subpoenas in 1997 and 2000. Indeed, Abbott lodged lengthy objections to the 2000 subpoena and ultimately ignored it, undermining the government's effort to conduct the investigation. (*See, e.g.*, Lavine Decl. at Ex.

64) (August 28, 2000 from Christopher Cook to Mark Lavine and Linda Hiller)). Abbott's counsel met with the government several times during the investigation to discuss the allegations. (*See, e.g.*, Lavine Decl. at Ex. 65) (November 3, 1999 letter from T. Reed Stephens to Daniel Reidy, referencing an October 27, 1999 presentation by the government to Abbott and its counsel)). In addition, Abbott was a member of a coalition of defendants who sought to discourage the United States from intervening in the matter. (*See, e.g.*, Lavine Decl. at Ex. 61) (March 17, 2000 Memorandum from Defendants Arguing Against Intervention) and Ex. 62 (September 1, 2000 letter from Daniel Reidy on behalf of Abbott joining in the Defendants' March 17, 2000 Memorandum)). Abbott had communications with the government about the subpoena, settlement and potential intervention from 1996 through the government's intervention in this matter. In addition, by this time Abbott had received letters from both the Department of Justice (1999) and a member of Congress (2000) accusing it of committing fraud.

77. On March 21, 2003, the United States and Relator filed an *ex parte* Joint Status Report and Joint Application to Extend Seal and Intervention Period. The application sought to extend the seal, noting that the United States was "participat(ing), "assist(ing)," and "support(ing)" the "prosecution of related claims by certain states on behalf of their State Medicaid Programs," including "parallel cases being pursued in California, Nevada, Minnesota, New York, and West Virginia." (Ex. DK at 4 & n. 1 (ABT008-1948-53).) Subsequent applications to extend the seal period likewise referenced the United States' continued participation, assistance, and support of related, parallel state cases, including cases against Abbott. (Ex. DL at 4-5 & n. 2 (ABT008-1838-44) (Aug. 2003); Ex. DM at 4 & n.2 (ABT008-1821-26) (Dec. 2003); Ex. DN at 4-5 (ABT008-1810-16) (Apr. 2004); Ex. DO at 4 (ABT008-1798-1804) (Sept. 2004); Ex. DP at 4-5 (ABT008-2385-91) (Mar. 2005); Ex. DQ at 5-6 (ABT008-2354-62) (Jul. 2005).)

United States' Response: The United States disputes the materiality of the above statement. Applications to extend the seal in FCA cases are filed *ex parte* pursuant to the FCA. *See* 31 U.S.C. § 3730(b)(3). The *ex parte* filing was appropriate and lawful. Further, Abbott was aware of the investigation by January 1996, and received HHS-OIG subpoenas in 1997 and 2000. Indeed, Abbott lodged lengthy objections to the 2000 subpoena and ultimately ignored it,

undermining the government's effort to conduct the investigation. (*See, e.g.*, Lavine Decl. at Ex. 64) (August 28, 2000 from Christopher Cook to Mark Lavine and Linda Hiller)). Abbott's counsel met with the government several times during the investigation to discuss the allegations. (*See, e.g.*, Lavine Decl. at Ex. 65) (November 3, 1999 letter from T. Reed Stephens to Daniel Reidy, referencing an October 27, 1999 presentation by the government to Abbott and its counsel)). In addition, Abbott was a member of a coalition of defendants who sought to discourage the United States from intervening in the matter. (*See, e.g.*, Lavine Decl. at Ex. 61) (March 17, 2000 Memorandum from Defendants Arguing Against Intervention) and Ex. 62 (September 1, 2000 letter from Daniel Reidy on behalf of Abbott joining in the Defendants' March 17, 2000 Memorandum)). Abbott had communications with the government about the subpoena, settlement and potential intervention from 1996 through the government's intervention in this matter. In addition, by this time Abbott had received letters from both the Department of Justice (1999) and a member of Congress (2000) accusing it of committing fraud.

78. On April 22, 2004, the United States and Relator filed an *ex parte* Joint Status Application to Extend Seal and Intervention Period for Certain Defendants. It stated: "The United States has retained three teams of accounting and data analysis experts to assist both with settlement negotiations and the overall investigation." (Ex. DN at 2 (ABT008-1810-16).) Subsequent motions to extend the seal indicated that the United States' rationale for extending the seal, among other reasons, was so that it could "prepare damages analyses." (Ex. DO at 4 (ABT008-1798-1804) (Sept. 2004); Ex. DP at 3 (ABT008-2385-91) (Mar. 2005); Ex. DQ at 4 (ABT008-2354-62) (Jul. 2005).)

United States' Response: The United States disputes the materiality of the above statement. Motions to extend the seal in FCA cases are filed *ex parte* pursuant to the FCA. *See* 31 U.S.C. § 3730(b)(3). The *ex parte* filing was appropriate and lawful. Further, Abbott was aware of the investigation by January 1996, and received HHS-OIG subpoenas in 1997 and 2000. Indeed, Abbott lodged lengthy objections to the 2000 subpoena and ultimately ignored it, undermining the government's effort to conduct the investigation. (*See, e.g.*, Lavine Decl. at Ex.

64) (August 28, 2000 from Christopher Cook to Mark Lavine and Linda Hiller)). Abbott's counsel met with the government several times during the investigation to discuss the allegations. (*See, e.g.*, Lavine Decl. at Ex. 65) (November 3, 1999 letter from T. Reed Stephens to Daniel Reidy, referencing an October 27, 1999 presentation by the government to Abbott and its counsel)). In addition, Abbott was a member of a coalition of defendants who sought to discourage the United States from intervening in the matter. (*See, e.g.*, Lavine Decl. at Ex. 61) (March 17, 2000 Memorandum from Defendants Arguing Against Intervention) and Ex. 62 (September 1, 2000 letter from Daniel Reidy on behalf of Abbott joining in the Defendants' March 17, 2000 Memorandum)). Abbott had communications with the government about the subpoena, settlement and potential intervention from 1996 through the government's intervention in this matter. In addition, by this time Abbott had received letters from both the Department of Justice (1999) and a member of Congress (2000) accusing it of committing fraud.

V. PROFFERED TESTIMONY OF MARK G. DUGGAN, PH.D.

79. In their initial disclosures, Plaintiffs stated that they would rely upon expert testimony to calculate damages attributable to their False Claims Act and common law fraud causes of action. (Ex. DR at 3-4.) In response to Abbott' interrogatories on the subject of damages, Plaintiffs indicated that they would rely upon expert testimony to calculate damages attributable to their False Claims Act, common law fraud, and unjust enrichment causes of action. (Ex. DS at 36-43.)

United States' Response: The cited references do not support the assertions in the above statement. The initial disclosures state that there were different damages theories that applied to the defendants' false price reporting conduct and the resulting harm to the Medicaid Programs. One of the damages theories stated in the initial disclosures was that the damages were equal to the full amount of the reimbursement paid in connection with the defendant's products. The initial disclosures also indicated that the plaintiffs had engaged experts to explore alternative damage theories.

80. On June 19, 2008, Plaintiffs served the expert report of Mark G. Duggan, Ph.D. (Ex. DT, Report of Mark G. Duggan, Ph.D., June 19, 2008 ("Duggan Rpt.").) Dr. Duggan is a Professor of Economics at the University of Maryland.

United States' Response: Undisputed. Further responding, the United States incorporates by reference and counter-designates through the Declaration of Mark Duggan filed in support of the United States' Motion for Summary Judgment.

81. Before proffering expert opinion in the AWP litigation brought by the state of Texas, Dr. Duggan had never been retained to provide expert testimony in a court of law. (Ex. DU, M. Duggan Dep. at 37:5-39:18.) Apart from AWP litigation, Dr. Duggan has never been engaged to assess damages in civil litigation. (*Id.* at 41:6-13.) Dr. Duggan has never had a damage calculation accepted by a court of law or jury. (*Id.* at 376:3-7.)

United States' Response: Undisputed. Further responding, the United States notes that Dr. Duggan has also never had a damage calculation rejected by a court of law or jury.

82. In his initial June 19, 2008 report, Dr. Duggan summarized his expert opinion as follows:

> This Report calculates a **$108.2 million difference** between (1) what the federal government reimbursed for certain pharmaceutical products provided to Medicaid and Medicare recipients during the eleven-year period 1991 and 2001 and (2) what the federal government would have reimbursed for the same products during the same time period if prices reflective of the actual prices at which Abbott was transacting business had been used for the AWP, WAC, and Direct Price of Abbott products.

(Ex. DT, Duggan Rpt. at 2.) On January 23, 2009, Plaintiffs served a supplemental expert report from Dr. Duggan that, among other things, removed Ohio from his "difference" analysis; this reduced his total "difference" figure from $108.2 million to $107.1 million. (Ex. DV, Supplement to Mark G. Duggan, Ph.D. Report, January 23, 2009 ("Duggan Suppl. Rpt.") at 2.) $64.7 million of Dr. Duggan's "difference" relates to the federal portion of Medicaid claims; $42.4 million relates to Medicare claims. (*Id.* at 2.) Dr. Duggan's initial report also "calculates that 2.30 million payments to health care providers would have been lower and 13.21 million claims would have resulted in lower Medicare or Medicaid spending had alternative prices been used for the AWP, WAC, and Direct Price of certain Abbott products during the relevant time period." (Ex. DT, Duggan Rpt. at 2.)

United States' Response: The United States does not dispute that Abbott has accurately, but selectively, quoted the first paragraph of the Executive Summary included in Dr. Duggan's

June 19, 2008 report. The entirety of the report is the best evidence of its contents and the summary set forth therein. The United States does not dispute that, on January 23, 2009, it served a supplement to the report of Dr. Duggan that, among other things, removed Ohio from the Medicaid analysis of his June 19, 2008 report. The United States does not dispute that Abbott has accurately, but selectively, quoted portions of the supplement to the report. The entirety of the supplement to the report is the best evidence of its contents. The United States does not dispute the remaining portions of the above statement.

83. When asked whether he was proffering expert testimony on the extent to which the federal government was damaged by Abbott's alleged misconduct in this case, Dr. Duggan provided the following testimony:

> Q. So it's your understanding that in this litigation you have been retained by the plaintiffs to calculate damages–
>
> MR. LAVINE: Object to form.
>
> Q. –is that right?
>
> A. There are many things in this litigation that I've been involved in doing and it is my understanding that my analysis certainly touches on the issue of damages. But that's just one of–as I try to outline in my report, there are other things that I set out to do as well.
>
> (Ex. DU, M. Duggan Dep. at 42:1-11.)
>
> * * *
>
> Q. For the time periods and products that you do consider in your calculation, are you yourself providing an opinion on the amount at which the federal government has been damaged by Abbott's alleged misconduct in this case?
>
> Mr. Lavine: Object to form.
>
> A. So once again, in the report I try to be very transparent about what exactly I'm doing. And one thing that I make clear is that-that I try very hard to make clear is that I'm not advocating the reporting of a specific product for a specific time period and so forth. But my analysis does what it states that it sets out to do, which is to calculate the difference plugging in the prices that I do for AWPs and so forth. And so it is-given all of the supporting narrative and analyses in my report, the $108.2 million difference represents what it says in the very first

sentence. So it doesn't fit-the problem is that I have this analysis which doesn't fit neatly into the question-"

(*Id.* at 44:8-49:6.)

* * *

A. . . . Now, as I said, this value of difference can be an important input or even the–an important input to damage or even the value of damage itself.

(*Id.* at 81:10-12.)

* * *

Q. You're not representing that the damages analysis that you perform is the whole picture, are you?

MS. THOMAS: Objection.

MR. LAVINE: Object to form.

A. I believe that the analyses that are summarized in my report are a very useful–represent a useful piece of information using a method that is readily accepted in my profession of holding other factors constant how different would spending by the federal government be. So it is–will there be issues other than my report that–it's hard for me to speculate what things–what issues jurors, the court and others with an interest in the case will deem relevant.

(*Id.* at 357:7-357:21.)

United States' Response: The United States does not dispute that Abbott has accurately quoted portions of Dr. Duggan's deposition testimony. The entire transcript of the deposition is the best evidence of its contents.

B. Duggan's Computation of Revised Prices

84. For each quarter during the Q1 1991 to Q4 2001 time period, and for each of the 44 National Drug Codes at issue ("Complaint NDCs"), Dr. Duggan calculated the revised AWPs, WACs, and DPs that are used in his "difference" calculations. Dr. Duggan calculated revised AWPs, WACs, and DPs by considering certain Direct and Indirect transaction data produced by Abbott. Dr. Duggan's report stated that he calculated the revised AWPs used in his "difference" calculation by "tak(ing) 125 percent of the average pharmacy indirect price in Abbott's indirect data as the benchmark for AWP." (Ex. DT, Duggan Rpt. at 37.) Dr. Duggan provided the following testimony concerning this approach:

> Q. Why did you scale up by 25 percent?
>
> A. I believe that I discussed this earlier in the report, that my examination of the data revealed that for most of the 44 products in most periods the AWP was 25 percent greater than the WAC, wholesaler acquisition cost. And so even though-so basically here even though the average price at which wholesalers are selling is typically much less than 25 percent greater than the price at which wholesalers are acquiring products, I used this 25 percent scaling factor that First Databank had in effect.

(Ex. DU, M. Duggan Dep. at 614:8-615:15.)

United States' Response: The cited references do not support Abbott's assertions in the first two sentences of the above statement. The United States does not dispute that Abbott has accurately, but selectively, quoted portions of page 37 of Dr. Duggan's June 19, 2008 report. The entirety of the report is the best evidence of its contents and the summary set forth therein. For example, as a counter-designation, the United States refers to page 9 of the report where Dr. Duggan states as follows:

> An examination of the published prices for the Abbott products listed in the Complaint indicates that the AWP is typically 125 percent of the WAC. My own analysis of Abbott's indirect and direct transaction data reveals the difference between the price at which wholesalers and distributors acquire Abbott products and the corresponding price at which they sell the products is on average much less than 25 percent. Despite this, I take the conservative approach of replacing the AWP with 125 percent of the average pharmacy indirect price for each NDC in each quarter, and determine how spending by the Medicaid and Medicare programs would have changed if these alternative prices had been used when adjudicating claims for both programs. I do the same for the Direct Price, though in this case I replace it with Abbott's average, pharmacy-specific price in the direct transaction data.

In addition, the United States does not dispute that the Abbott has accurately, but selectively, quoted portions of the deposition of Dr. Duggan. The entire transcript is the best evidence of its contents.

85. Dr. Duggan has not proffered an opinion on what prices Abbott should have reported. (Ex. DU, M. Duggan Dep. at 193:7-195:19; 563:12-14.) Although Dr. Duggan calculated

various pricing parameters for the 44 Complaint NDCs (e.g., a 95th percentile price), Dr. Duggan used the 50th percentile price that he calculated, scaled up by 25% in computing his revised AWP, in his "difference" calculation. (*Id.* at 412:16-421:15.) Dr. Duggan has not proffered an opinion on which percentile price should be used in his "difference" calculation. (*Id.* at 427:17-430:5.)

United States' Response: The United States does not dispute that Dr. Duggan has not proffered an opinion on what prices Abbott should have reported. The United States disputes that Dr. Duggan used the 50th percentile price to compute a revised AWP and disputes that he has not proffered an opinion on which percentile price should be used in his "difference" calculation. Rather, Dr. Duggan's analysis in this regard was performed by replacing the AWP with 125 percent of the weighted average pharmacy indirect price for each NDC in each quarter. Page 9 of Dr. Duggan's June 19, 2008 report.

86. Table 1 of Dr. Duggan's report listed his computation, using Abbott's direct transaction data, of the average price paid for each of the 44 Complaint NDCs for the third quarter of 1996 (for two NDCs, he uses a computation for the third quarter of 1999). (Ex. DT, Duggan Rpt. at Table 1.) For 37 of the 44 Complaint NDCs, his average price is less than $2 per package. (*Id.*) For 29 of the 44 Complaint NDCs, Dr. Duggan's average price is less than $1 per package. (*Id.*)

United States' Response: The United States disputes the above statement. The fifth column of Table 1 of Dr. Duggan's June 19, 2008 report lists the average per package price for each NDC calculated by dividing the sum of total sales and chargebacks for each NDC by the sum of the total quantity (ICQTY) transacted for that NDC over the entire 11-year period from 1991 to 2001. In the sixth and seventh columns of Table 1, Dr. Duggan then calculates an overall estimate of the spreads on Abbott's NDCs by comparing the 11-year average prices to the 1996 published AWPs and Direct Prices (except for two NDCs where he used the 1999 published AWPs and Direct Prices to calculate the spreads because that was the first time that AWPs and Direct Prices were published for those NDCs). In particular, in the sixth column of Table 1, Dr. Duggan reports

the ratio of the Direct Price in the third quarter of 1996 to Abbott's average price during the 11-year period, while in the seventh column he reports report the analogous ratio using the Average Wholesale Price (AWP) in the third quarter of 1996 in the numerator. In further response to this paragraph, the United States does not dispute that the average prices at which Abbott was selling these products to all classes of trade for 37 of the 44 NDCs was less than $2.00, and for 29 of the NDCs was less than $1.00.

C. Duggan's Sample Selection

87. In his June 19, 2008 report, Dr. Duggan performed separate Medicaid "difference" calculations for twelve states: Illinois, Florida, California, New Jersey, New York, Indiana, Kentucky, Missouri, Ohio, Michigan, Louisiana, and Wisconsin. (Ex. DT, Duggan Rpt. at 30-76.) In his January 23, 2009 supplemental report, Dr. Duggan removed any "difference" attributable to Ohio from his total "difference" calculation. (Ex. DV, Duggan Suppl. Rpt. at 1.) Dr. Duggan's "difference" calculation for the state of Indiana does not rely upon claims data produced by Indiana Medicaid. (Ex. DT, Duggan Rpt. at 54-55; Ex. DU, M. Duggan Dep. at 249:20-250:5; 486:8-16.)

United States' Response: The United States does not dispute the first two sentences of paragraph 87. Further responding, the United States notes that the entirety of the report and the supplement to the report is the best evidence of its contents. The United States disputes the third sentence of Abbott paragraph 87. Dr. Duggan's "difference" calculation for the state of Indiana does rely upon claims data produced by Indiana Medicaid. (Duggan Declaration, ¶¶ 12-16).

88. In the final version of his Medicaid "difference" calculation, Dr. Duggan calculated a separate "difference" calculation for the following ten states: Illinois, Florida, California, New Jersey, New York, Kentucky, Missouri, Michigan, Louisiana, and Wisconsin. (Ex. DV, Duggan Suppl. Rpt. at 2.) The "difference" findings for these ten states are extrapolated to 38 other states. (*Id.*) Dr. Duggan separately calculated a "difference" for Indiana by extrapolating his "difference" findings from Illinois. (Ex. DT, Duggan Rpt. at 55-58.)

United States' Response: The United States does not dispute paragraph 88. Further responding, the United States notes that the entirety of the report and supplement to the report is the best evidence of its contents.

89. The ten states for which Dr. Duggan separately calculated a "difference" (the findings of which are extrapolated to 38 other states) were not chosen at random. (Ex. DW, Mark G. Duggan, Ph.D. Rebuttal Report - April 23, 2009 ("Duggan Reb. Rpt.") at 14 ("the 10 are not a random sample of the initial 48").) Dr. Duggan chose those states for which he performed separate "difference" calculations principally based on the amount of expenditures the states had on the 44 Complaint NDCs. Dr. Duggan provided the following testimony:

> Q. Did you ask the Department of Justice to get claims data for all 50 states for all of the years in the claim period for all of the NDCs?
>
> A. Around this specific time or just generally?
>
> Q. At any point.
>
> A. I believe that I requested especially data for the states that accounted for a disproportionate share of Medicaid spending on complaint products. For example, Illinois. For example, Florida. And so forth.
>
> Q. And why did you–
>
> A. And so–just to clarify–
>
> Q. Sure.
>
> A. –so I certainly recall requesting data for those large states.
>
> Q. Did you not want claims data for all 50 states?
>
> A. I believe that if-I wasn't opposed to having data for other states, but I felt for the purposes of my analysis it would be-just a sort of diminishing returns sense. It would be most important to start with the places that account for the largest amount of Medicaid spending.

(Ex. DU, M. Duggan Dep. at 242:20-243:21.)

United States' Response: The United States does not dispute the first two sentences of paragraph 89, but notes that the states were selected on the basis of articulated factors, and that Dr. Duggan has demonstrated those states to be representative of the other states. (Duggan Declaration,¶¶ . 13-14, 17, 71-90). As a further response, the United States notes that the entirety

of the rebuttal report is the best evidence of its contents. The United States does not dispute that Abbott has accurately, but selectively, quoted portions of the deposition of Dr. Duggan. The entire transcript is the best evidence of its contents. In addition, other factors were considered in addition to the amount of expenditures, such as the quality of the data. (Duggan Declaration, ¶¶ 13-14, 17, 71-90).

90. CMS has published guidance and direction for Medicare carriers which use "statistical sampling in their reviews to calculate and project (*i.e.*, extrapolate) overpayment amounts to be recovered by recoupment, offset or otherwise." (Ex. DY, CMS Manual System, Pub. 100-08, Medicare Program Integrity, Transmittal 114, *Change in Statistical Sampling Instructions* ("Transmittal 114") at 3.10.1.1; see also Ex. DZ, Program Memorandum Carriers, Transmittal B-03-022, *Use of Statistical Sampling for Overpayment Estimation When Performing Administrative Reviews of Part B Claims* (March 21, 2003) ("Transmittal B-03-022").) The guidance is "provided to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project an overpayment where the results of the review indicate that overpayments have been made." (Ex. DY, Transmittal 114 at 3.10.1.1.) Transmittal 114 states that the sampling methodology used to project overpayments must be reviewed by a statistician, or by a person with equivalent expertise in probability sampling and estimation methods. (*Id.* at 3.10.1.5 (Consultation with a Statistical Expert).) Medicare Carriers must obtain written approval of the methodology for the type of statistical sampling to be performed. (*Id.*) Transmittal 114 states that the Carrier "shall maintain complete documentation of the sampling methodology that was followed." (*Id.* at 3.10.4.4 (Documentation of Sampling Methodology); *see also* Ex. DZ, Transmittal B-03-022 at IV.D ("You must provide complete documentation of the sampling methodology that you followed.").)

United States' Response: The United States does not dispute paragraph 90. Further responding, the United States does not dispute that the defendant has accurately, but selectively, quoted portions of the referenced documents. The documents in their entirety are the best evidence of their contents.

91. Dr. Duggan did not document what sampling methodology, if any, that he employed in extrapolating his "difference" calculations from one set of states to another set of states.

United States' Response: The United States disputes the above statement. Every step of Dr. Duggan's methodology has been documented and presented in a fashion that allowed for it to

be replicated by the defendants. (Duggan Declaration, ¶¶ 13-14, 17, 71-90). The defendants have been able to replicate the work done by Dr. Duggan. *See* Report of Steven Young, Abbott Exhibit EO.

92. Transmittal 114 states: "For statistical sampling for overpayment estimation, one of the possible samples is selected by a random process according to each sampling unit in the target population receives an appropriate chance of selection. The selection probabilities do not have to be equal but they should be all be greater than zero." (Ex. DY, Transmittal 114 at 3.10.2.) Transmittal 114 further states: "The universe and sampling frame will usually cover *all relevant claims or line items for the period under review*." (*Id.* at 3.10.3.2) (emphasis added). Transmittal 114 further states: "**Part B Claims**: The universe shall consist of all fully and partially paid claims submitted by the supplier for the period selected for review and for the sampling units to be reviewed. For example, if the review is of Physician X for the period January 1, 2002 through March 31, 2002, and the laboratory and other diagnostic tests have been selected for review, the universe would include all fully and partially paid claims for laboratory and diagnostic tests billed by that physician for the selected time period."

United States' Response: The United States does not dispute the above statement. As a further response, the United States does not dispute that Abbott has accurately, but selectively, quoted portions of the referenced documents. The documents in their entirety are the best evidence of their contents.

93. Except for the states of Illinois, Florida, California, New Jersey, New York, Kentucky, Missouri, Michigan, Louisiana, and Wisconsin, Dr. Duggan's Medicaid "difference" calculation did not rely on claims data produced by state Medicaid agencies. (Ex. DU, M. Duggan Dep. at 249:15-250:5.) Therefore, no claims paid by states other than Illinois, Florida, California, New Jersey, New York, Kentucky, Missouri, Michigan, Louisiana, and Wisconsin are included in the Medicaid "difference" findings that Dr. Duggan extrapolated to other states.

United States' Response: The United States disputes the above statement. All of Dr. Duggan's calculations for every state relied upon claims data produced by state Medicaid agencies. (Duggan Declaration, ¶¶ 12-16).

94. Dr. Duggan worked with Steck Consulting and Patrick Ormond of the United States Attorney's Office in Boston to obtain claims data from state Medicaid programs to be used in his "difference" analysis. (Ex. DU, M. Duggan Dep. at 251:2-252:2.)

United States' Response: Undisputed.

95. Dr. Duggan previously served an expert report for the state of Texas against Abbott related to drug pricing litigation. (Ex. DU, M. Duggan Dep. at 41:14-22.) Dr. Duggan became familiar with Texas Medicaid claims data by virtue of this work in the Texas AWP case against Abbott; he discussed data issues with personnel from Texas Medicaid. (*Id.* at 109:15-112:14.) Approximately half of the 44 Complaint NDCs were also at issue in the Texas AWP litigation against Abbott. (*Id.* at 494:6-9.)

United States' Response: The United States does not dispute the above statement except to clarify the Dr. Duggan served as an "expert" for the State of Texas (he did not serve an "expert report").

96. In the National Pharmaceutical Council's November 1997 *Pharmaceutical Benefits Under State Medicaid Assistance Programs* publication, the state of Texas is ranked third in the amount of Medicaid drug payments for 1996. (Ex. EA (Abbott Ex. 1113); Ex. DU, M. Duggan Dep. at 481:21-482:4.) It was also ranked third in 1995.

United States' Response: The United States does not dispute the above statement. As a further response, the United States does not dispute that Abbott has accurately, but selectively, quoted portions of the referenced publication. The document in its entirety is the best evidence of its content.

97. Dr. Duggan and/or his consultants received claims data for the 44 Complaint NDCs from Texas Medicaid covering the time period of 1996 through 2006. (Ex. EB at EXP USABT-DUG 147479 (Abbott Ex. 1115); Ex. DU, M. Duggan Dep. at 488:8-489:1.)

United States' Response: Undisputed.

98. Dr. Duggan did not utilize the claims data produced by Texas Medicaid to perform a separate "difference" calculation for Texas. Therefore, Texas is not included in the ten-state "difference" findings that Dr. Duggan extrapolated to other states. When asked why he did not prepare a separate "difference" analysis of Texas for this case, using claims data produced by Texas Medicaid, Dr. Duggan gave the following testimony:

Q. Is there a reason why Texas was not included in your 11 states because it was only-because it had less expenditures for the complaint products?

A. That isn't the only reason. That is – I considered many factors when determining which states to include. So for example Wisconsin is number 17 in terms of SDUD spending. And I consider that partly because the data went back so far in time. As I recall Wisconsin went back to–let me check here in my report. It went back to early '93, which wasn't true for many of the states for which we obtained data.

Q. Any other reasons you can enunciate here today why you did not include Texas in your 11 states or–when I say 11 states I mean the-what term should I use for that? Claims data states? Would that work?

A. You can say "the eleven."

Q. "The eleven"? So when I say that–

A. Yeah. I think we're on the same page if you just say "the eleven." So my recollection is that in the case of Texas it was a combination of the fact that utilization–you know, Texas isn't Alaska. Alaska has–or Washington, D.C., they have very low utilization. But they have lower utilization for these products than the other states that I did consider. So total spending was one factor. How much data we had was another factor. Those were two of the more important–I would want to go back and look at was there anything else. But those were two factors that certainly loomed large. . . .

(Ex. DU, M. Duggan Dep. at 492:8-493:19.)

United States' Response: The United States does not dispute the above statement except to clarify that Dr. Duggan did utilize claims data produced by Texas Medicaid, but did not perform a separate "difference" calculation for Texas as was done for the other ten states referenced by Abbott. The United States does not dispute that Abbott has accurately, but selectively, quoted portions of the referenced deposition, but states that the entire transcript is the best evidence of its content.

99. Dr. Duggan was aware that Texas frequently implemented MACs on many of the 44 Complaint NDCs during times relevant to his "difference" analysis. (Ex. DT, Duggan Rpt. at 33 fn. 24 ("For example, some states used SMAC prices for one or more Complaint products at some time during the period of interest. This frequently occurred in the Texas

Medicaid program for Abbott products . . . ."); Ex. DU, M. Duggan Dep. at 504:14-505:1).)

United States' Response: The United States does not dispute that Abbott has accurately, but selectively, quoted portions of the referenced report. The entire report is the best evidence of its contents.

100. In the National Pharmaceutical Council's November 1997 *Pharmaceutical Benefits Under State Medicaid Assistance Programs* publication, the state of Pennsylvania Medicaid program is ranked fifth in the amount of drug payments for 1996. (Ex. EA (Abbott Ex. 1113); Ex. DU, M. Duggan Dep. at 531:17-532:13.) It was also ranked fifth in 1995.

United States' Response: Undisputed.

101. Dr. Duggan and/or his consultants received claims data for the 44 Complaint NDCs from Pennsylvania Medicaid covering the time period of 1998 through 2007. (Ex. EB (Abbott Ex. 1115) at EXP USABT-DUG 147479; Ex. EC (Abbott Ex. 1117); Ex. DU, M. Duggan Dep. at 532:17-534:9.)

United States' Response: The United States does not dispute the above statement except to clarify that Dr. Duggan did utilize claims data produced by Pennsylvania Medicaid, but did not perform a separate "difference" calculation for Pennsylvania as was done for the other ten states referred to by the defendant. Further responding, the United States does not dispute that the defendant has accurately, but selectively, quoted portions of the referenced deposition, but states that the transcript in its entirety is the best evidence of its contents.

102. Dr. Duggan did not utilize the claims data produced by Pennsylvania Medicaid to perform a separate "difference" calculation for Pennsylvania. Therefore, Pennsylvania is not included in the ten-state "difference" findings that Dr. Duggan extrapolated to other states. When asked why he did not prepare a separate "difference" analysis of Pennsylvania, using claims data produced by Pennsylvania, Dr. Duggan gave the following testimony:

> Q. And you do not have a separate–I'll state it another way. Pennsylvania is not one of the 11 states, correct?
>
> A. That's correct.
>
> Q. Do you know why not?
>
> A. As I said earlier, I considered at least two factors–well, I guess at least three factors–when determining whether to add, let's

> say, a state. One was did we have data from it. Two was is it large amount of Medicaid spending. And three, how much coverage do we have for the state. And so here we can see Pennsylvania has– of the 11 states I considered, Pennsylvania's spending is higher only than Wisconsin. But for Wisconsin the data went back all the way to 1993. And so it is–my sense is that for the same sort of diminishing returns reason one has to draw the line somewhere. If one works from the bottom of the table up, Washington D.C., Vermont, Alaska, those aren't on the sort of cusp. I drew the line where I felt was appropriate given the data that was available and those other issues.
>
> * * *
>
> Q. You did utilize-or included in your 11 states are states that had less claims data than Pennsylvania, though, am I right?
>
> A. Only Wisconsin. Well, actually, Wisconsin has more claims.
>
> Q. Years of claims data.
>
> A. Correct. So it would a sort of two pronged decision.
>
> Q. Like for the state of Michigan you had claims data only starting in the fourth quarter of 2000, right?
>
> A. I don't recall. That sounds right.
>
> Q. Missouri you had claims data starting in the first quarter of 1998, right?
>
> A. That's correct. That's what I recall. So inevitably when one draws the line there's going to be a state that's close to the line and, you know, on either side. And Pennsylvania was a state– Washington D.C. wasn't close to the line. Pennsylvania was. But I drew the line where I felt it was appropriate.

(Ex. DU, M. Duggan Dep. at 534:10-536:18.)

United States' Response: The United States does not dispute the above statement except to clarify that Dr. Duggan did utilize claims data produced by Pennsylvania Medicaid, but did not perform a separate "difference" calculation for Pennsylvania as was done for the other ten states referred to by the defendant. As a further response, the United States does not dispute that the

Defendant has accurately, but selectively, quoted portions of the referenced deposition, but states that the transcript in its entirety is the best evidence of its contents.

103. During times relevant to Dr. Duggan's "difference" analysis, Pennsylvania Medicaid determined MAC pricing "by one of the following methods:

> (1) For multisource drugs not classified as HCFA multisource drugs, the Department will set the State MAC at the BaseLine Price for that multisource drug entity as determined and provided by the Department's pricing service.
>
> (2) For drugs classified as HCFA multisource drugs, the Department will set the State MAC at the federal upper limit established for that drug."

(Ex. ED (Abbott Ex. 322) at HHC007-0980 (Pennsylvania state plan, Effective Oct. 1, 1995).) BaseLine Price is a pricing methodology for multiple source products developed in or around 1994 by First Databank, the goal of which was to develop a "consistent, nationally recognized, mechanical pricing methodology." (Ex. EE (Abbott Ex. 323) at TX-ABT_00013723.) The methodology that First Databank used to develop the BaseLine price is set forth in Ex. EE (Abbott Ex. 323) at TX-ABT_00013728-30. First Databank published Baseline Prices for certain of the 44 Complaint NDCs, including for Abbott's vancomycin. (*E.g.*, Ex. EF at FDB-AWP (1995 Baseline Price for Abbott 500 mg of vancomycin).)

United States' Response: The United States does not dispute that Abbott Ex. ED is a copy of pages 1 and 2 of Attachment 4.19-B of the State Plan Amendment for the Medicaid Program for the State of Pennsylvania with an effective date of October 1, 1995. Abbott has correctly, but selectively, quoted excerpts of the State Plan Amendment. The entirety of that Attachment is the best evidence of its content. The United States does not dispute that Abbott Ex. EE is an excerpt from Appendix Q of the NDDF User Manual. However, the United States disputes Abbott's selective quotation from Ex. EE because Abbott has taken the quote out of context. The statement quoted by Abbott was part of First Databank's explanation that "a consistent, nationally recognized, mechanical pricing methodology which would be fair to third party payors and their providers has yet to be developed." Ex. EE also states that "prices have become the subject of controversy as selected manufacturers inflate their prices, and pharmacy providers dispense products with inflated Average Wholesale Prices (AWPs) in an effort to

maximize prices." In addition, Ex. EE does not specifically articulate the goal of First Databank, but states that First Databank had tried to create a "standardized pricing methodology which takes all of these factors into account." The United States disputes that Ex. EF contains an accurate copy of page 1 to the 1995 Bluebook because the bottom half of the entire first page is illegible, the original of which contained a definition of AWP as "the published suggested wholesale price obtained from the manufacturer or the price commonly charged by wholesaler as determined by survey.", and also explained the "OBRA" designation in the Blue Book was used to identify the companies "that have signed a medicaid rebate agreement with HCFA to supply rebates to the states based on the utilization of their products. Manufacturers may join the program or leave it as they desire. Only products from those manufacturers with a signed rebate agreement need be covered under the medicaid programs." The data here represents the manufacturers with rebate agreements as of January 1995. The bottom half of the page also explained that the Baseline Price was derived by calculating the "mean average for all NDCs in a specific product group, determining the standard deviation, and calculating a new mean average using all products within one standard deviation of the original mean average." Thus, the baseline price for vancomycin contained in Exhibit EE appears to be at least partially based on drugs manufactured by companies other than Abbott and is not specific to Abbott's NDCs. A legible copy of the pages contained in Ex. EE is contained in Exhibit AB to the Lavine Declaration.

104. Through a third-party subpoena, Abbott received claims data from the Maryland Department of Health and Mental Hygiene ("DHMH") for the 44 Complaint NDCs for the time period from 1991 to 2001. Counsel for Abbott sent the Maryland claims data to the DOJ via email on August 14, 2007. (Ex. EG (Aug. 14, 2007 D. Torborg email).) On August 16, 2007, the DOJ advised Dr. Duggan of the availability of this claims data, which the DOJ had forwarded to Steck Consulting, a consulting expert retained by the Plaintiffs. (Ex. EH at EXP USABT-DUG 057015-16.)

United States' Response: Undisputed.

105. Maryland DHMH began establishing MAC pricing for dextrose, sodium chloride, vancomycin, and other injectable products in 1995 and 1996. (Ex. EI (Abbott Maryland Ex. 12); Ex. V, J. Fine Dep. at 188:3-190:17; Ex. EJ, F. Tetkoski Dep. at 116:9-127:12; Ex. EK (MD0021454-97); Ex. V, J. Fine Dep. at 193:2-194:10.) To establish its MAC pricing during the period from December 1994 to June 2003, DHMH utilized acquisition cost pricing information from pharmacy providers. (Ex. EL (Abbott Maryland Ex. 15); Ex. V, J. Fine Dep. at 200:11-204:7.) DHMH did not use prices reported in the compendia to establish its MAC pricing. (*Id.*) Maryland DHMH's MAC pricing levels for dextrose, sodium chloride, and vancomycin prices were much lower than the prices determined through its estimated acquisition cost methodology. (See, e.g., Ex. EL (MD0005721).)

United States' Response: The United States disputes the above statement. Although Mr. Fine testified that Maryland added injectable drugs to the Interchangeable Drug Costs (IDC) List in 1995, he did not identify which drugs were included on the list at that time. Further, Mr. Fine testified that, in setting its IDC prices, Maryland generally did not rely on compendia prices; rather, Maryland relied on wholesale price lists that it obtained either from local wholesalers or pharmacies because it believed that wholesale acquisition costs represented the true price at which pharmacies could purchase such drugs. Mr. Tetkoski testified that when such wholesale prices were not available, Maryland could rely on compendia prices to set IDC prices. Mr. Fine also testified that Maryland had no knowledge of what individual providers paid for drugs. To the extent that drugs such as dextrose, sodium chloride or vancomycin were included on an IDC list, the IDC prices could have been lower, higher or the same as what the prices would have been had it used the EAC methodology.

106. Dr. Duggan did not utilize the claims data produced by Maryland DHMH to perform a separate "difference" calculation for Maryland. Therefore, Maryland is not included in the ten-state "difference" findings that Dr. Duggan extrapolated to other states.

United States' Response: Abbott has failed to cite to any record support for the above statement. Nonetheless, the United States does not dispute the statement except to clarify that Dr. Duggan did utilize claims data produced by Maryland Medicaid, but did not perform a separate

"difference" calculation for Maryland as was done for the other ten states referred to by the defendant.

107. In first quarter of 1997, Maryland had a state MAC for NDC 00074653301 (Vancomycin 1 gm vial) of $9.63. (Ex. EK (MD0021496); Ex. EJ, F. Tetkoski Dep. at 117:9-124:5.) For the first quarter of 1997, the "DIFF-FRAC" that Dr. Duggan utilized in his extrapolation for NDC 00074653301 was .809104. (See Duggan electronic production, filename mgd-feb13\dta\ten.dta.) For the first quarter of 1997, Dr. Duggan's calculated acquisition cost for NDC 00074653301 is $5.85. (*See* Duggan electronic production, filename ABBOTT-20080618-S-0001\from_duggan_to_steck\mgd-final\indirect\dta\ph9101stats.dta.)

United States' Response: The United States disputes the first sentence of paragraph 107. On pages 117-124, Mr. Tetkoski testified that it appeared to him that by December 15, 1997, Maryland had established a MAC for certain dextrose products. The United States does not dispute the second and third sentences of the above statement.

108. Ohio was originally included the set of states for which Dr. Duggan performed a separate "difference" calculation, the results of which were extrapolated to 38 other states. Dr. Duggan observed in his initial report that the "ratio of DIFFERENCE to the total amount of Medicaid spending is substantially lower in Ohio than in the preceding states," and that "[t]his is largely driven by the state's more frequent use of MACs, which serves to reduce the discrepancy between Abbott's actual prices and those used by the state when adjudicating Medicaid claims." (Ex. DT, Duggan Rpt. at 67.) Dr. Duggan also stated in his initial report that Ohio was the only state to produce claims data for all 44 quarters at issue and, because Ohio "has a low value of DIFFERENCE relative to the total amount paid," "it will have a greater weight than other states which provided data for fewer." (*Id.* at 79.) When Plaintiffs disclaimed damages from Ohio, Dr. Duggan removed the impact of Ohio completely from his "difference" analysis, which served to increase the total "difference" Dr. Duggan calculated for the 38 extrapolated states. (Ex. DV, Duggan Suppl. Rpt. at 2 ("Additionally, I no longer use the state of Ohio in my analyses for the remaining 38 states, and thus the results in Tables 27A and 27B have also changed.").) Dr. Duggan removed Ohio from his "difference" analysis "based on instructions that (he) received from counsel." (Ex. DU, M. Duggan Dep. at 647:9-10.)

United States' Response: Undisputed. Further responding, the United States does not dispute that Abbott has accurately, but selectively, quoted portions of the referenced report. The entirety of the referenced report is the best evidence of its content.

109. The Medicaid "difference" analysis that Dr. Duggan performed depended, in part, on the availability of claims data. Dr. Duggan gave the following testimony:

> Q. My question was not what the results-what you think your results would have been if you had data for all 50 states throughout the claim period for all NDCs. It was whether or not you would have preferred to have claim data for all 50 states and for all the time period. That's the question.
> MS. THOMAS: Objection.
> A. I believe that in my analysis I did precisely what I preferred given the available data and so forth. So can the caveat that-and so I guess I won't discuss the issue I just mentioned. But I did exactly the analysis that I wanted to do, taking all factors into account.
> Q. And one of the factors was the availability of the data, correct? Yes or no?
> MR. LAVINE: Objection to form.
> A. It would depend on the specific state. But I believe that for some states in some time periods that would be true.

(Ex. DU, M. Duggan Dep. at 245:19-246:15.)

> * * *
> A. . . . So, for example, suppose they contacted Vermont and perhaps Vermont did not have data going back to 2001 or earlier. That's just an example. I don't recall that specifically. And so at my direction they initiated these calls and acquired as much data as they could from states. And I believe that one factor influencing whether or not data was obtained was just the availability of data, whether the state Medicaid agency or its contractor had the data. That I believe was one factor.

(*Id.* at 251:18-252:2.)

United States' Response: The United States does not dispute the first sentence of paragraph 109. Further responding, the United States does not dispute that the Defendant has accurately, but selectively, quoted portions of the deposition of Dr. Duggan. The entire transcript is the best evidence of its contents.

110. To assess the comparability of the states, Dr. Duggan compared the Medicaid adjudication formulas used by the states. Dr. Duggan's report states:

> My comparison of the Medicaid adjudication algorithms used by the 11 states described above with the 38 remaining states suggests that the two groups are very similar. The vast majority of states in both groups use AWP during the eleven-year period, though some also use the WAC and the DP. More specifically, of the 11 states for which I use state Medicaid claims data above, 8 used AWP for most or all of the period with the remaining three primarily using either the WAC or the DP. During this same period, 30 of the remaining 38 states primarily relied on AWP while the remaining 8 used either the WAC or the DP. Additionally,

> virtually all of the states consider the provider charged amount, taking the lesser of this and the amount that results from applying the adjudication formula.

(Ex. DT, Duggan Rpt. at 78-79.)

United States' Response: The United States does not dispute the first sentence of the above statement, or that Abbott has accurately, but selectively, quoted portions of Dr. Duggan's June 19, 2008 report. The entirety of the report is the best evidence of its contents.

111. During at least some portion of the 1991 to 2001 time period, five states (Alaska, Georgia, Massachusetts, Rhode Island, and Vermont) defined the "usual and customary" charge to include the lowest price paid by third party payers. Dr. Duggan did not perform separate "difference" calculations for any of these five states. None of the ten states for which he performed separate "difference" calculations defined the "usual and customary" charge to include the lowest price paid by third party payers during the 1991 to 2001 time period.

United States' Response: The United States does not dispute that Alaska, Georgia, Massachusetts and Rhode Island generally defined the "usual and customary" charge to include the lowest price paid by third party payers. Further responding, the United States notes that Vermont defined U&C as the charge to the general public. (Lavine Decl. at USAbt-J, A. Rugg Dep. at. 135-136 and 138-41).

112. In preparing his initial report, Dr. Duggan used SMRF/MAX data from 1999 to 2001 to compare the average amount spent per claim between the eleven states (where he used claims data) and the remaining 38 states (for which he does not use claims data produced by state Medicaid programs). (Ex. DT, Duggan Rpt. at 78-79, fn. 45). He testified that he conducted this analysis in order to consider the question of selection bias. (Ex. DU, M. Duggan Dep. at 497:21-498:15.) When Dr. Duggan performed this analysis, Ohio-which had the lowest "ratio of DIFFERENCE" of the eleven states-was included in the analysis. (Ex. DT, Duggan Rpt. at 78-79, fn. 45; (Ex. DU, M. Duggan Dep. at 501:2-5 ("A. . . . So I considered that very issue, the sample selection issue, and it is-at some level Ohio is the biggest outlier in terms of average reimbursement per prescription. And that holds when you drill down to specific NDCs. But I considered that and I actually gave that state disproportionate weight in my analysis even though at some level it has the lowest reimbursement. And giving Ohio disproportionate weight relative to the other ten states in my subsequent analyses is certainly favorable to Abbott.").) Dr. Duggan did not produce a revised version of this analysis when he removed Ohio from his "difference" calculation. He provided the following testimony on this point:

> Q. What analysis have you done to consider whether your removal of Ohio from the detailed claims data set has on your per claim analysis that you reflect in

footnote 45?

A. On average, the ratio of difference to Medicaid spending for Ohio is about 50 percent compared with about 75 percent for the others. It is one of the ten states utilized in that. So it will pull down somewhat. But I have not updated footnote 45.

(Ex. DU, M. Duggan Dep. at 281:18-282:13.)

United States' Response: The United States disputes the first sentence of the above statement because it does not accurately characterize Dr. Duggan's methodology regarding the use of SMRF/MAX, as set forth in his report. As a result, the record citation does not support the factual assertion. Dr. Duggan used the SMRF/ MAX data as only one element of his methodology. The United States disputes the second sentence of the statement because it does not accurately set forth Dr. Duggan's testimony at 497:21-498:15, and as a result, the record citation does not support that factual assertion. With regard to the second sentence, the United States submits that this statement is not material where the United States is moving to dismiss its claims against Abbott pertaining to the Ohio Medicaid program. The deposition testimony cited by Abbott predates the United States' motion. Moreover, Dr. Duggan no longer takes Ohio into account for his damages model. (*See* Duggan Supplemental Report, Abbott Ex. DV to Torborg Declaration at p. 2). The United States does not dispute that Abbott has accurately, but selectively, quoted portions of the deposition of Dr. Duggan. The entire transcript is the best evidence of its contents.

113. Dr. Duggan gave the following additional testimony about the analysis referenced in footnote 45 of his initial June 19, 2008 report:

Q. So for 20 of the 44 NDCs your analysis found the 38 states paid less per claim than the 11 states, correct?

A. Yes. That's what it says in the footnote.

Q. Now, why would that happen?

> MS. THOMAS: Objection to form.
>
> A. And I should also note that–just to clarify something you said–that the 24 where the opposite was true account for 75 percent of the spending. But it could be true because-there are a number of reasons why it could be true. One would be the importance of the dispensing fee may differ between two states for two pairs of drugs. So for example you may have a drug, two states, one with a dispensing fee of 5, the other with a dispensing fee of 3, and, you know, there could be something else about the formula that would differ between two states for two pairs of drugs. So for example you may have a drug, two states, one with a dispensing fee of 5, the other with a dispensing fee of 3, and, you know, there could be something else about the formula that would differ. There are just many factors. It could be something about the dispensing fee, something about the ingredient cost reimbursement, the number of units, the price that's being used and so forth. So there are a number of factors that could produce that.

(Ex. DU, M. Duggan Dep. at 525:3-526:2.)

United States' Response: The United States does not dispute the first sentence of the above statement, nor does the United States dispute that the above paragraph purports to recite a portion of Dr. Duggan's testimony. Abbott has selectively quoted portions of the deposition of Dr. Duggan. The entire transcript is the best evidence of his testimony.

114. Dr. Duggan did not analyze whether the number of units per claim is consistent across the states. (Ex DU, M. Duggan Dep. at 690-91.) A 2002 Myers and Stauffer report prepared for California shows significant variability in how many units of intravenous drugs that pharmacies would include in their claims. In particular, the report stated:

> There is some difficultly, however, in determining an average dispensing cost. . . . There is a significant inconsistency in the way in which pharmacies count the number of intravenous prescriptions dispensing. A pharmacy may mix and delivery many 'dispensing' of a daily intravenous solution from a single prescription, thus incurring additional costs spread over a smaller number of prescriptions. Alternatively, some pharmacies count each daily dispensing individually.

(Ex. Y, Myers and Stauffer Study of Medi-Cal Pharmacy Reimbursement at 59-60.)

United States' Response: The United States disputes the first sentence of the above statement because it does not accurately set forth Dr. Duggan's testimony at 690-691, and as a

result the record citation does not support that factual assertion. The United States further does not dispute that Abbott accurately and selectively quotes from Ex. Y at p. 59-60, however, the entire document is the best evidence of its content.

115. When asked to summarize what all he did to assess the comparability of the eleven states for which he originally calculated separate "differences," which he then extrapolated to 38 other states, Dr. Duggan provided the following testimony:

> Q. Okay. As you sit here today can you tell me, apart from the analysis you discuss in footnote 45 and the analysis that you discuss that you just testified about and the comparison of the number of times states used AWP versus other measures, anything else that you did to compare the 11 states to the 38 states?
>
> A. I mean, nothing is leaping to mind right now, but it doesn't mean I didn't do other things. It's just hard to recall everything that went into this. But these are the two things that I felt were very important to mention. But there may be-I don't think there are others mentioned elsewhere in the report. But I would need to go back and look at it. But I don't recall. To answer your question, I don't recall.
>
> Q. And you don't know if you did any comparison of the type you discuss in footnote 45 for the years 1991 through 1998; isn't that right?
>
> MS. THOMAS: Objection to form.
>
> A. Yeah. I don't recall.

(Ex. DU, M. Duggan Dep. at 520:18-521:16.)

United States' Response: The United States disputes the first clause of the above statement because it does not accurately or completely summarize Dr. Duggan's testimony at 520-521, and as a result the record citation does not support that factual assertion. The United States does not dispute that Abbott has accurately, but selectively, quoted portions of the deposition of Dr. Duggan. The entire transcript is the best evidence of its contents.

116. In his June 19, 2008 report, Dr. Duggan performed separate Medicare "difference" calculations for four Durable Medical Equipment Carriers ("DMERCs") (Palmetto, AdminaStar, CIGNA, and Travelers) and for seven Part B carriers (Connecticut General, WPS, Other Region 5, KY AdminaStar, WV Nationwide, Other Metra Health, and Florida Blue Shield). (Ex. DT, Duggan Rpt. at 84-123, Tables 33 & 34.) The "difference" findings from these Part B carriers are extrapolated to other Part B carriers. (*Id.* at

123-26.)

United States' Response: The United States does not dispute the first sentence of the above statement or that Abbott has accurately, but selectively referenced portions of Dr. Duggan's June 19, 2008 report. The entirety of the report is the best evidence of its contents. With regard to the second sentence of SOF 116, the United States disputes Abbott's characterization of the difference findings, but does not dispute that Dr. Duggan performed an extrapolation, which are referenced, in part, at those designated pages of his and submits that the entirety of Dr. Duggan's report is the best evidence of its contents.

117. The Part B carriers for which Dr. Duggan separately calculates a "difference" were not chosen at random. Dr. Duggan has not documented what sampling methodology, if any, that he employed in extrapolating his "difference" calculations from one set of Part B carriers (which produced arrays) to another set of Part B carriers (which did not produce arrays). Dr. Duggan relied upon pricing arrays supplied to him by the DOJ. The Government has asserted privilege over correspondence between the DOJ and Medicare carriers concerning attempts to gather information, such as pricing arrays, used in the prosecution of this case. (*E.g.*, Ex. EM (Carrier Privilege Log - Documents Covered by Attorney-Client Privilege or Work Product Doctrine).)

United States' Response: The *"E.g."* example citation to Exhibit EM to the Torborg Declaration is not evidence and fails as proper record support for the above statement. Abbott offers no other record support for the purported, and argumentative, factual allegations set forth in the above statement. For these reasons, the United States disputes the above statement. The evidence in this case relied upon by Dr. Duggan is delineated in his reports and testimony, which together in their entirety, provide the best evidence regarding the factual predicates Dr. Duggan relied upon in forming his opinions in this case.

118. Two experts retained by Abbott, Dr. James W. Hughes (a Professor of Economics at Bates College) and Mr. Steven J. Young (an accountant with considerable healthcare consulting experience), have heavily criticized the extrapolation methodologies employed by Dr. Duggan. Those criticisms can by found on pages 41-46 (Medicaid) and 18-20 (Medicare) of Dr. Hughes's report and pages 14-21, 25-26 (Medicaid), and 21-22 (Medicare) of Mr. Young's report. (Ex. EN (Expert Report of James W. Hughes); Ex. EO (Expert Report of

Steven J. Young).)

United States' Response: The United States does not dispute that Abbott has retained Dr. James W. Hughes and Dr. Young as experts in this case, and that they have criticized Dr. Duggan's methodologies. The United States further submits that the pages of Dr. Hughes' and Dr. Young's reports speak for themselves, but they are hearsay and are not evidence in this case.

D. Duggan's Medicaid "Difference"

119. Dr. Duggan relied upon the accounting firm of Myers and Stauffer to acquire information about the adjudication formulas used by state Medicaid programs to provide payments to providers for dispensing pharmaceuticals to Medicaid patients. (Ex. DU, M. Duggan Dep. at 114:8-21, 118:14-18.) To assist Dr. Duggan, Myers and Stauffer prepared schedules for each state Medicaid program titled, "Medicaid Pharmacy Reimbursement Methodology." (*E.g.*, Ex. AS (California Medicaid Pharmacy Reimbursement Methodology).)

United States' Response: The United States does not dispute the first sentence of the above statement or that Abbott has accurately cited Dr. Duggan's testimony. The entirety of those documents are the best evidence of its contents.

120. Dr. Duggan did not ask Myers and Stauffer to determine what state Medicaid programs meant when they used the terms Average Wholesale Price, Wholesale Acquisition Cost, or Direct Price in their adjudication formulas, or how state Medicaid programs defined those terms in their state plans. (Ex. DU, M. Duggan Dep. at 731:9-734:21.) ("Q. Do the Myers and Stauffer summaries contain information about how the state defined average wholesale price in its state plan? Mr. Lavine: Object to form. A. Not that I recall, except we talked about First Databank where they obtained their information.").) Dr. Duggan did not ask Myers and Stauffer to determine what state Medicaid programs understood about the relationship between compendia AWPs and actual acquisition costs. (*Id.* at 735:4-736:20) ("A . . . [W]hat the knowledge was of various government officials was not the focus of my analysis, and was not something that I instructed them [Myers and Stauffer] to do.").) Dr. Duggan did not ask Myers and Stauffer to evaluate whether states intended to pay a margin between providers' acquisition costs and the amount paid in reimbursement for the Complaint NDCs. (*Id.* at 738:7-14.) ("Q. Did you ask Myers and Stauffer to inquire of the states whether they wanted to pay a margin between the acquisition cost providers and the amount that they paid reimbursement for the complaint NDCs?

Mr. Lavine: Objection to form.

The Witness: I did not ask them to do that.").) Dr. Duggan did not ask Myers and

Stauffer to inquire of state Medicaid programs if they believed their dispensing fees were adequate to cover the cost of dispensing the Complaint NDCs. (*Id.* at 751:13-19.)

United States' Response: The United States disputes the characterizations of Dr. Duggan's testimony in the above statement because it does not accurately set forth Dr. Duggan's testimony at pp. 731-736 and 738 of the transcript, and as a result the record citation does not support that factual assertion. The United States does not dispute that Abbott has accurately, but selectively, quoted portions of the deposition of Dr. Duggan at 731-736 and 738, but states that the entire transcript is the best evidence of its contents.

121. For each of the claims upon which he computes a "difference," Dr. Duggan did not analyze whether the claim was paid based upon any price reported in the compendia. (Ex. DU, M. Duggan Dep. at 762:7-764:3.) Dr. Duggan did not determine the payment basis for all claims upon which he computes a "difference" in any state. (*Id.*)

United States' Response: The United States disputes the first sentence of the above statement because it does not accurately set forth Dr. Duggan's testimony at 762-764, and as a result, the record citation does not support that factual assertion. The United States disputes the statement because it mischaracterizes Dr. Duggan's method, which is more fully set forth in Dr. Duggan's expert reports. Torborg Decl. Exs. DV, DW and DT.

122. Dr. Duggan did not analyze which Medicaid programs established MAC pricing for the 44 Complaint NDCs or when all such MAC pricing was in effect. Dr. Duggan did not ask Myers and Stauffer to determine which states established MAC pricing for the 44 Complaint NDCs. (Ex. DU, M. Duggan Dep. at 750:10-751:11) ("Q. Did you ask them specifically, I want you to bear down on these 44 NDCs and see if there is a MAC on those products? Mr. Lavine: Object to form. The Witness: No. . . . I did not ask them to catalogue what time periods and what-you know, what NDC quarter combinations might there have been a MAC in effect."). (*See also Id.* at 765:7-765"18 and 789:7-789:9).

United States' Response: The United States disputes the characterizations of Dr. Duggan's testimony in the first sentence of the above statement because it mischaracterizes Dr. Duggan's testimony at 750, and as a result, the record citation does not support that purported

factual assertion. Dr. Duggan clearly explained that he was testifying about his communications with Myers and Stauffer and not whether and to what extent he undertook his actual analysis. Moreover, with respect to sentence two, the best evidence of what directions Dr. Duggan gave to Myers and Stauffer is in the entire deposition transcript. The United States disputes the second sentence of the above statement, because it is patently inconsistent with Dr. Duggan's testimony. As a result, the record citation does not support the purported factual assertion. The United States does not dispute that the statement accurately, but selectively, quoted portions of the deposition of Dr. Duggan at 731-736 and 738. The entire transcript is the best evidence of its contents.

123. Dr. Duggan did not analyze what impact, if any, that AWPs, WAC, or DPs reported in the compendia had on the MAC pricing established by any state Medicaid program. (Ex. DU, M. Duggan Dep. at 791:5-8, 794:11-16.)

United States' Response: The United States disputes the first sentence of the above statement. Dr. Duggan's testimony at 791 and 794 does not in any way suggest that "Dr. Duggan did not analyze what impact, if any, that AWPs, WAC, or DPs reported in the compendia had on the MAC pricing established by any state Medicaid program", and as a result the record citation does not support that factual assertion. The testimony of Dr. Duggan explains simply that the determination of MAC prices is not something that Dr. Duggan exhaustively studied, and that Dr. Duggan does not know all of the processes used by states to establish MACs.

124. Dr. Duggan's "difference" calculation for Medicaid claims includes a "difference" for claims that were, in fact, based on a maximum amount MAC. Dr. Duggan gave the following testimony:

> Q. And there are instances where states had a MAC on the complaint products, correct?
>
> A. Yes. That is my understanding. Correct.
>
> * * *
>
> Q. Why don't you eliminate claims that were paid on the maximum allowable

cost from other states besides Ohio?

MR. LAVINE: Object to form.

THE WITNESS: As I discuss-I believe I discuss in the report, in some cases, a MAC may be in effect, but if, let's say, the AWP fell below, if the reimbursement amount would be lower using the published AWP for a product, that AWP would, in those cases, be used in place of the MAC.

BY MR. TORBORG: Q. And in those instances, situations you described, you would be calculating a difference between the MAC amount and your but-for AWP driven price, correct?

A. I mean, essentially, what my analysis would do-would do that to some extent. Essentially what my analysis would do would be to determine whether the reimbursement amount using, let's say, an alternative AWP would fall below the reimbursement amount using the MAC-MAC price.

Q. So you would calculate difference in those situations? You potentially might, correct?

A. Correct.

(Ex. DU, M. Duggan Dep. at 651:1-652:17.) Mr. Duggan gave the following additional testimony on point:

Q. Now, for situations where there was a MAC on one of the 44 NDCs in a particular quarter, the amount that was paid by the Medicaid program is not based on the reported price of the Abbott product, correct?

MR. LAVINE: Object to form.

THE WITNESS: That's an input in it, but if ultimately what-if the MAC results in a lower amount paid than would result if the AWP were used, then the AWP isn't used-it is used, right, it's used in the adjudication formula, but it is, it's not the one on which the ultimate payment amount is based.
Q. And there are instances where you're still calculating a difference, right? In those instances, right?

A. That is correct. And in some cases, it may be zero.

(*Id.* at 765:19-766:15.)

United States' Response: The United States disputes the first sentence of the above statement because it does not accurately characterize Dr. Duggan's testimony, and as a result, the

record citation does not support that factual assertion. The United States does not dispute that Abbott has accurately, but selectively, quoted portions of the deposition of Dr. Duggan. The entire transcript is the best evidence of its contents.

125. The Myers and Stauffer reimbursement summary for the state of Minnesota, prepared for Dr. Duggan for this litigation, stated the following regarding the methodology Minnesota used to establish state MACs:

> SMACs are based on an informal survey of a few retail pharmacies that have agreed to share their costs. The State tries to include an average profit of about $7.00 for each prescription using SMAC. This $7 includes the $3.65 dispensing fee. . . .

(Ex. AS (Myers and Stauffer Medicaid Pharmacy Reimbursement Methodology for Minnesota) (emphasis added); see also Ex. EP (Abbott Duggan Ex. 3). When asked if he was aware that Minnesota followed this approach to setting MAC pricing, Dr. Duggan provided the following testimony:

> Q. Were you aware that Minnesota tried to include an average profit of $7 for each prescription when it set a SMAC?
>
> MR. LAVINE: Object to form.
>
> THE WITNESS: No. I was not aware.

(Ex. DU, M. Duggan Dep. at 781:22-782:4.)

United States' Response: The United States does not dispute that the above statement accurately, but selectively, quotes portions of Torborg Decl. Ex. EP. That document pertains to a single state and the entire document is the best evidence of its contents. The United States does not dispute that Abbott has accurately, but selectively, quoted portions of the deposition of Dr. Duggan. The entire transcript is the best evidence of its contents.

126. Dr. Duggan did not evaluate whether state Medicaid programs intended to set MAC pricing above what the state believes it costs the average pharmacist to purchase the drug. Dr. Duggan provided the following testimony:

> Q. When a state sets a MAC-let me ask you this. You are aware of the fact, are you not, Professor Duggan, that states across the country in establishing MACs don't often just set it at the acquisition price, right?

MS. THOMAS: Objection. Form.
THE WITNESS: It may vary somewhat across states and over time, how exactly they arrive at a MAC.

Q. Are you aware of the fact that there are states across the country who set a MAC price at above what it thinks it costs the average pharmacist to purchase the drug? Are you aware of that evidence?

MR. LAVINE: Object to the form.

THE WITNESS: The determination of MAC prices is not something that I exhaustively studied in this, so I certainly am aware of certain cases where that might have been true.

(Ex. DU, M. Duggan Dep. at 790:11-791:8.)

* * *

Q. Is it not possible that state Medicaid programs and providers engaged in a process where they looked at proposed MAC levels, considered all the issues that might go into drug payment policy and decided on a MAC level that was fair and workable?

MR. LAVINE: Object to form.

THE WITNESS: It is possible. It's just not an area that has been the focus of my analysis.

(*Id.* at 795:4-13.)

United States' Response: The United States disputes the first sentence of the above statement because it does not accurately characterize Dr. Duggan's testimony, and as a result, the record citation does not support that factual assertion. Dr. Duggan testified that "It's just not an area that has been the focus of my analysis." The United States does not dispute that Abbott has accurately, but selectively, quoted portions of the deposition of Dr. Duggan. The entire transcript is the best evidence of its contents.

127. Dr. Duggan's initial report separately explained the methodology that he used to separately calculate "differences" for the states of Illinois, Florida, California, New Jersey, New York, Kentucky, Missouri, Michigan, Louisiana, and Wisconsin for those time periods where those states produced detailed claims data. First, using the claims data, he identified the total number of claims for one of the 44 Complaint NDCs and then removes those claims with apparent data errors. (*E.g.*, Ex. DT, Duggan Rpt. at 30, 32-33 (Illinois).)

Second, Dr. Duggan developed a computer algorithm that purports to reflect the states' adjudication methodologies, using the information contained in the Myers and Stauffer reimbursement schedules. (*Id.* at 31-32.) Third, he linked each of the states' claims for one of the 44 Complaint NDCs with a NDC-quarter-specific prices that he calculated. He utilized the prices he calculated from the three pharmacy classes of trade in Abbott's transaction data. (*Id.* at 34.) Fourth, Dr. Duggan then purported to use his computer algorithm re-adjudicate those claims using his revised prices. (*Id.* at 34.) Anytime there is a difference between what the state paid on a claim and what it allegedly would have paid had Dr. Duggan's revised prices been used, Dr. Duggan computed a "difference" on that claim. (*Id.*) For example, Dr. Duggan calculated a "difference" for claims reimbursed on the basis of a provider usual and customary charge ("U&C") or state MAC if his revised estimated acquisition cost price results in a price lower than the U&C or MAC. (Ex. DT, Duggan Rpt. at 33 fn. 24; Ex. DU, M. Duggan Dep. at 651:1-652:17.) CMS did not establish Federal Upper Limits ("FULs") on any of the 44 Complaint NDCs during the time period of Dr. Duggan's analysis.

United States' Response: The United States does not dispute the first sentence of paragraph 127, and adds that the entirety of Dr. Duggan's initial report is the best evidence of its contents. The United States does dispute that the remainder of paragraph 127 fully and accurately characterizes Dr. Duggan's methodology, and submits that the entirety of Dr. Duggan's initial report is the best evidence of its contents, and that the entirety of all of Dr. Duggan's reports in this case and his expert testimony properly set forth and explain his methodology to varying degrees. Torborg Decl. Ex. DU, DT, DV, & DW.

128. For none of the ten states for which Dr. Duggan separately calculated a "difference" (Illinois, Florida, California, New Jersey, New York, Kentucky, Missouri, Michigan, Louisiana, and Wisconsin) does he utilize claims data covering the entire time period of his analysis (Q1 1991 through Q4 2001). Dr. Duggan used claims data produced by the states for the following time periods of his "difference" calculation: Illinois (Q2 1991 - Q4 2001), Florida (Q4 1993 - Q4 2001), California (Q2 1994 - Q4 2001), New Jersey (Q1 1992 - Q4 2001), New York (Q1 1993 - Q4 2001), Kentucky (Q1 1995 - Q4 2001), Missouri (Q1 1998 (Q1 1995 - Q4 2001), Michigan (Q4 2000 (Q1 1995 - Q4 2001), Louisiana (Q1 1995 - Q4 2001), and Wisconsin (Q3 1993 - Q4 2001). Table 25 of Dr. Duggan's initial report separately identified those periods within these states for which his "difference" calculation was based upon the use of claims data produced by the states. (Ex. DT, Duggan Rpt. Table 25.)

United States' Response: The United States disputes the above statement. Dr. Duggan utilized claims data for every period for which he calculated damages. (Duggan Decl. ¶¶ 12-19).

The United States does not dispute that Abbott accurately describes the time periods for which Dr. Duggan had data collected directly from the states which was primarily used to separately calculate the difference between what was paid out by those states as compared to what would have been paid had their reimbursement been based upon the alternative prices calculated by Dr. Duggan. The entirety of all of Dr. Duggan's reports in this case and his testimony set out and explain his methodology. Torborg Decl. Ex. DU, DT, DV, & DW.

129. With the exception of California and Illinois, Dr. Duggan computed a "difference" for every quarter in the Q1 1991 to Q4 2001 time period for the ten states for which he separately calculates a "difference." Dr. Duggan's report described the methodology that he employed to calculate "differences" for those quarters where claims data were not produced from the ten states. (E.g., Ex. DT, Duggan Rpt. at 42-44 (Florida).) Dr. Duggan referred to this methodology as "Within State Extrapolation." (Ex. DW, Duggan Reb. Rpt. at 10.) Dr. Duggan's Within State Extrapolation computes a "ratio of DIFFERENCE" for the earliest quarter where he has claims data produced by the state. The "ratio of DIFFERENCE," or "difference ratio," reflects the percentage by which a states' spending for a specific NDC-quarter allegedly would have changed had Dr. Duggan's revised prices had been used in a states' adjudication methodology. (Ex. DT, Duggan Rpt. at 42.) Dr. Duggan then scaled down this ratio of DIFFERENCE to account for the possibility that the spread between reported prices and marketplace prices would have been less in earlier periods. (*Id.*) On an NDC-quarter basis, he applies this scaled ratio of DIFFERENCE to a state's putative spending for the 44 Complaint NDCs. (*Id.*) He utilizes aggregate data maintained by CMS, State Drug Utilization Data ("SDUD") and SMRF/MAX, to determine a state's putative spending for the 44 Complaint NDCs. (*Id.*) Table 25 of Dr. Duggan's initial report separately identifies those periods within the ten states for which his "difference" calculation is based upon his Within State Extrapolation methodology. (*Id.* at Table 25.)

United States' Response: The United States does not dispute that Dr. Duggan relied upon claims data collected directly from the states together with data that had been collected from the states by CMS in order to perform his analysis of additional damages described in the above statement as the "Within State Extrapolation." However, Dr. Duggan utilized claims data for every period for which he calculated damages, including within state and interstate extrapolations. (Duggan Decl. ¶¶ 12 -19 and 60-108). The entirety of all of Dr. Duggan's reports in this case and his testimony set out and explain his methodology. Torborg Decl. Ex. DU, DT, DV, & DW.

130. For those time periods when Dr. Duggan had claims data for the ten states for which he separately calculates a "difference," Dr. Duggan determined the percentage of claims that were reimbursed on the basis of provider charges. (*E.g.*, Ex. EQ (Excerpts from Duggan STATA log for Illinois.) Dr. Duggan's working papers show variability within a given state over time in the percentage of claims reimbursed at charges, and a general decline across the states in the percentage of claims reimbursed on that basis. (*E.g.*, *Id.*) In Illinois, Dr. Duggan's analysis shows that the percentage of U&C-based reimbursements declined from 76.90% in 1992 to 12.76% in 2001. (*Id.*)

The United States' Response: The United States does not dispute that the excerpts from Dr. Duggan's STATA log in Ex EQ reflect variability over time for claims paid at U&C by Illinois Medicaid but dispute that the Exhibit reveals any such trend across states. However, to the extent that a summary of the data reveals such a trend, it is explained by the increased enforcement efforts of the United States with respect to drug prices used to determine Medicaid payments.

131. Dr. Duggan calculated a difference for 38 states by "extrapolating" his "difference" findings from Illinois, Florida, California, New Jersey, New York, Kentucky, Missouri, Michigan, Louisiana, and Wisconsin. (Ex. DT, Duggan Rpt. at 77-81; Ex. DV, Duggan Suppl. Rpt. at 2.) Pages 77 through 81 of Dr. Duggan's initial report explained this "Across State Extrapolation" methodology. (Ex. DT, Duggan Rpt. at 77-81, Ex. DW, Duggan Reb. Rpt. at 12.)

United States' Response: The United States does not dispute that Dr. Duggan employed proper extrapolation techniques but disputes that his calculations for the 38 states were limited to extrapolations as he applied the CMS data-set types to calculate differences for specific states, specific NDCs, specific claims amounts. (*See, e.g.*, DW, Duggan Reb. Rpt. at 11; Duggan Decl. ¶¶ 37-90).

132. On an NDC-quarter basis, Dr. Duggan computed an average ratio of DIFFERENCE from his ten-state analysis. (Ex. DT, Duggan Rpt. at 78.) Dr. Duggan also referred to this value as a "DIFF-FRAC." (*Id.*) The "DIFF-FRAC" is a composite ratio of DIFFERENCE which represents the average ratio of the change in Medicaid spending that allegedly would have occurred if his revised prices had been used in the ten states' reimbursement calculations. (*Id.*) Each of the ten states which produced detailed claims data for an NDC-quarter was given equal weight in calculating the "DIFF-FRAC." States which did not produce any claims data for an NDC-quarter are given a weight of zero for that

NDC-quarter. (*Id.*)

United States' Response: Undisputed.

133. Dr. Duggan's Across State Methodology then relied on aggregate data maintained by CMS, SDUD or SMRF/MAX, to determine a state's putative spending for the 44 Complaint NDCs. (Ex. DT, Duggan Rpt. at 77-78, 80.) On an NDC-quarter basis, Dr. Duggan applied his "DIFF-FRAC" to the states' putative spending for each of the 44 Complaint NDCs, as reflected in the SDUD or SMRF/MAX data. (*Id.*) Dr. Duggan utilized the SMRF/MAX data when it was available. The results of Dr. Duggan's Across State Extrapolation Methodology are reflected in Tables 27A and 27B of his supplemental report. (Ex. DV, Duggan Suppl. Rpt.)

United States' Response: The United States does not dispute the above statement except that SMRF/MAX data is clams-level data and is not accurately referred to as simply aggregate data.

134. The SDUD data used in Dr. Duggan's Medicaid "difference" analysis identified, by NDC, the aggregate amount that a state paid each quarter to providers for dispensing that NDC. (Ex. DU, M. Duggan Dep. at 689:1-690:19.) The payment amounts included in the SDUD data included dispensing fees paid to providers. (*Id.* at 691:5-7.)

United States' Response: Undisputed.

135. The SMRF/MAX data used in Dr. Duggan's Medicaid "difference" analysis included a provider identifier and has information on the amount paid on a per-claim basis. (Ex. DU, M. Duggan Dep. at 700:8-18.) Like the SDUD data, however, the paid amount field in the SMRF/MAX data included dispensing fees paid to providers. (*Id.* at 701:12-16.) Neither the SDUD or SMRF/MAX data contained the information necessary to determine whether a claim was paid using a state MAC. (*Id.* at 704:11-19 ("Q. Does the SMRF MAX data allow you to determine whether or not a claim was paid using a MAC? Mr. Lavine: Object to form. A. I-there are many variables that are included in the SMRF MAX data, but if memory serves, that is not something that can be gleaned as easily as the sort of-was it paid at charged amount that we just talked about.").

United States' Response: The United States disputes the above statement. While it may not have been as easy to determine if a claim was paid using a state MAC using SDUD or SMRF/MAX data, Dr. Duggan did not say he was unable to effectively allow for state MACs to the extent material to his calculations. The SDUD or SMRF/MAX data together with other sources of information could be used to determine if a claim was paid using a state MAC.

136. In September of 2004, the Office of Inspector General ("OIG") issued a report titled *Variation in State Medicaid Drug Prices* (OEI-05-02-00681). The purpose of OIG's report was to "assess the extent to which States' Medicaid pharmacy reimbursement varies for the same drugs." (Ex. ER at i.) OIG evaluated fiscal year 2001 drug reimbursement data for 28 NDCs from 42 states. The 28 NDCs included 10 generic drugs and 28 brand name drugs. (*Id.* at ii-iii.) OIG found that, "[o]n average, the highest paying State paid 477 percent more per drug than the lowest paying State for each of the 28 drugs in our sample." (*Id.* at ii.) OIG found higher variability in the reimbursements for the ten generic drugs in the sample. It found median and average variations of 374% and 1230%, respectively, between the highest and lowest paying states. (*Id.* at 9-10). OIG also found that the "average difference between the State at the 25th percentile and the State the 75th percentile (i.e., the interquartile range) was 63 percent for the 10 non-innovator multisource drugs." (*Id.* at 10.) OIG attributed the variability in generic drug reimbursements to, among other things, the prevalence and differences in state MAC pricing, as well as differences in states' definitions of "usual and customary charge" and the frequency with which drugs were reimbursed at U&C. (*Id.* at 19-21.) OIG's report further observed: "Even States with the same formula for estimating pharmacy acquisition demonstrated variation in their average annual reimbursement prices." (*Id.* at I.)

United States' Response: The United States disputes the relevancy of the above statement but does not dispute that the OIG issued the report referenced therein. The entire report is the best evidence of its content.

137. Effective January 1, 1995, Kansas reimbursed "IV Fluids" at AWP - 50%. (Ex. AS, Myers and Stauffer Medicaid Pharmacy Reimbursement Methodology for Kansas; Ex. ES (Abbott Ex. 575).) A Policy Memorandum from Kansas Medicaid dated November 21, 1994 provided the following rationale for this methodology:
Discounts from the reference pharmaceutical pricing schedule known as Average Wholesale Price (AWP) vary by product class. Generally, intravenous vehicles and irrigation solutions are available at much greater discounts than are other pharmaceuticals. (Ex. ES (Abbott Ex. 575).)

United States' Response: Undisputed.

138. The AWP reported by First Databank for NDC 00074798436 on April 1, 1997 was $10.76. For the second quarter of 1997, the "DIFF-FRAC" that Dr. Duggan employed in his extrapolation for NDC 00074798436 is .829193 (Duggan electronic production, filename: mgd-feb13\dta\ten.dta).)

United States' Response: The United States does not dispute the above statement, but states further that the average pharmacy indirect price for 00074-7984-36 the second quarter of 1997 was $1.10 which resulted in a spread of approximately 880% when compared to the AWP.

(Ormond Decl., Attachment A-45, page 3 and Schedule B4, page 41).

139. Effective April 1, 2001, Utah implemented special category dispensing fees for NDCs covered by the revised pricing issued by the United States Department of Justice. (Ex. AS, Myers and Stauffer Medicaid Pharmacy Reimbursement Methodology for Utah; Ex. ET (HHC014-0833).) An April 2001 document titled "The Amber Sheet" prepared by the Utah State Medicaid DUR Committee stated:

> MULTIPLE DISPENSING FEES ASSOCIATED WITH HOME INFUSION PHARMACY SERVICES. The U.S. Department of Justice (DOJ) as part of a legal process, has established 'true' AWP for 437 NDC specific products and has directed the Division to implement this price list. Home infusion pharmacy services have low volume and high expenditures. The DOJ's price list place the 'true AWP' close to actual acquisition costs, thus eliminating the 'spread' or profit that pharmacies have enjoyed for years.

(Ex. ET (HHC014-0833).)

United States' Response: The United States does not dispute the above statement. Abbott has correctly, but selectively, quoted excerpts of that document. The entirety of the documents is the best evidence of its content.

140. Dr. Duggan and/or his consultants received claims data for the 44 Complaint NDCs from Pennsylvania Utah Medicaid covering the time period of 1998 through 2007. (Ex. EB (Abbott Ex. 1115) at EXP USABT-DUG 147481.) A claim with given a Steck_ID number of 11148089 is a Utah claim adjudicated on September 17, 2001 for three units of NDC 00074653301. (Ex. EU.) Utah allowed $50.04 on this claim. $22.90 of the $50.04 is included in a field titled "AllowedDispensingFee." (*Id.*) The DOJ AWP for NDC 00074653301 was $9.05. (Ex. AP at AWP010-0887 (Abbott Ex. 487).) For the third quarter of 2001, the "DIFF-FRAC" that Dr. Duggan employed in his extrapolation for NDC 00074653301 is 577262. (Duggan electronic production, filename: mgd-feb13\dta\ten.dta).)

United States' Response: The United States disputes the above statement because it erroneously states the information from the referenced sources. For example, it refers to "Pennsylvania Utah Medicaid"; fails to correctly place a decimal point in the DIF-FRAC, properly reflect the FDB unit AWP of $17.725, the Duggan calculated acquisition cost of $4.30 or the submitted charge of $372.33. (Ormond Decl., Attachment B3, page 4, Attachment B4, page 16).

141. There is variability in the dispensing, compounding, and other professional fees paid by

the state Medicaid programs during the Q1 1991 to Q4 2001 time period. The Myers and Stauffer reimbursement schedules prepared for Dr. Duggan and other documents evidence this variability, in that they show at least 17 states (Alaska, District of Columbia, Idaho, Maryland, Maine, Michigan, Minnesota, New Hampshire, Nevada, Ohio, Pennsylvania, South Carolina, Utah, Vermont, Washington, Wisconsin, West Virginia) paying some sort of enhanced professional fee for the dispensing of home infusion or compounded drugs. (Ex. AS, Myers and Stauffer Medicaid Pharmacy Reimbursement Methodology schedules; Ex. EV (Abbott Washington Ex. 2) at JDWA001687-88; Ex. EW (Abbott Ex. 1062); Ex. EO (Expert Report of Steven J. Young) at 19.)

- Minnesota paid an additional dispensing fee of $8.00 per bag for infusion drugs requiring compounding. (Ex. AS (Myers and Stauffer Medicaid Pharmacy Reimbursement Methodology for Minnesota).)
- Maryland paid a dispensing fee of $7.25 to $7.70 per day for home I.V. therapy prescriptions (versus the ordinary $4.21 per prescription fee). (Ex. AS (Myers and Stauffer Medicaid Pharmacy Reimbursement Methodology for Maryland); see also Ex. EX (Abbott MD 18); Ex. V, J. Fine Dep. at 224:3-225:18.)
- Nevada paid a dispensing fee of $16.80 for the first dose of an intravenous medication, and $5.60 for the second dose given concurrently. (Ex. AS, Myers and Stauffer Medicaid Pharmacy Reimbursement Methodology for Nevada.)
- When Utah implemented the DOJ AWPs, it created much higher dispensing-fee levels (up to $33.90) for the NDCs included within the DOJ AWPs. (Ex. AS, Myers and Stauffer Medicaid Pharmacy Reimbursement Methodology for Utah; see also Ex. ET (HHC014-0833).)

United States' Response: The United States does not dispute the above statements. Abbott has correctly, but selectively, quoted excerpts of the cited documents. The entirety of the documents are the best evidence of their content.

E. Duggan's Medicare "Difference"

142. Dr. Duggan's Medicare "difference" relates to five HCPCS codes, J3370 (500 mg Vancomycin HCL), J7030 (1000 ml normal saline), J7040 (500 ml normal saline), J7050 (250 ml normal saline solution), and J7060 (500 ml 5 percent Dextrose/Water). (Ex. DT, Duggan Rpt. Tables 33, 43 & 44.) Dr. Duggan's report stated that the goal of his Medicare "difference" analysis "is to determine the amount by which spending by the Medicare program on DME (and Carrier) claims would have changed if alternative prices had been used for Abbott products." (*Id.* at 82, 95.) Dr. Duggan's total $42.4 million "difference" attributable to Medicare did not limit the purported change in Medicare spending for the five J-Codes included in his analysis to Abbott's market share for the products.

United States' Response: Undisputed.

143. During times relevant to the Plaintiffs' Complaint, Medicare employed contractors to determine payment allowables and process claims for payment. Medicare employed Durable Medical Equipment Regional Carriers ("DMERCs") to process claims submitted by durable medical equipment suppliers, and Medicare Part B Carriers to process claims submitted by physicians. Table 35 of Dr. Duggan's report identified the Carrier codes of 92 different Carriers which processed claims for one of the five J-Codes included in Dr. Duggan's "difference" analysis. (Ex. DT, Duggan Rpt. at 96, Table 35.) Some Carriers had multiple codes. (*Id.*)

United States' Response: Undisputed.

144. Because the five J-Codes included in Dr. Duggan's analysis involved multiple-source drugs, the DMERCs and Carriers which processed these claims for payment utilized pricing arrays to determine "median AWP" figures. (Ex. DT, Duggan Rpt. at 81) ("Additionally, the payment amounts for each HCPCS code are determined by each insurance carrier (e.g. Palmetto), with the typical carrier using the median AWP of the NDCs included in the carrier's array as the per-unit allowed amount, with this changing to 95 percent of the median on January 1, 1998.").) Most DMERCs and Carriers revised their pricing arrays quarterly, pursuant to CMS's instructions. (Ex. EY at AWP037-001A.)

United States' Response: The United States does not dispute the first sentence of paragraph 144. With respect to Ex. EY, the United States does not dispute that Abbott has correctly, but selective, quoted excerpts of Ex. EY. The entire of Ex. EY is the best evidence of its content.

145. During times relevant to Dr. Duggan's analysis, there were numerous manufacturers, dosage sizes, and packaging offerings (*e.g.*, "flip-top" vial vs. "ADD-Vantage") included within the various arrays produced by DMERCs and Part B Carriers that Dr. Duggan considered in his Medicare "difference" analysis. For example, in its Q4 1999 array for J7050 (250 cc, normal saline solution), Palmetto included two 250 ml Abbott NDCs, one 500 ml Abbott NDC, one 1000 ml Abbott NDC, one 500 ml Compumed NDC, one 1000 ml Compumed NDC, one 500 ml McGaw NDC, one 1000 ml McGaw NDC, one 500 ml Phys Total Care NDC, and 1000 ml Phys Total Care NDC. (Ex. EZ (Myers and Stauffer revised array, filename: ARRAYs_PALMETO_J7050.xls Tab: 1999 Q4).) In his June 19, 2008 report, Dr. Duggan stated that the "NDCs that are included in an array vary across carriers and can vary within the same carrier over time." (Ex. DT, Duggan Rpt. at 82.)

United States' Response: The United States does not dispute the above statement. With respect to Ex. DT, the United States does not dispute that Abbott has correctly, but selectively quoted excerpts of Ex. DT. The entirety of Ex. DT is the best evidence of its content.

146. On January 11, 2002, Jing Xing Technologies, Inc. submitted a final report to CMS titled "Prices Established by Private and Public Sectors for Drugs Also Covered Under Medicare Part B." (Ex. FA (HHD128-0164-85.) The Jing Xing report subjected a subset of 20 HCPCS codes representing 65% of Medicare Part B drug expenditures for the year 2000 to a pattern analysis. The data was "analyzed for variations of allowable amounts (payment dollars) between carriers," and Jing Xing hypothesized as to the possible reasons for the variance. (*Id.* at HHD128-0176.) Moreover, "[e]ach of the carriers' sources of information was studied as well as their methods of calculation and the specific products they used." (*Id.*) Jing Xing's report included the following finding:

> **Carrier Variance in Calculating Allowable Amounts**
>
> A comparison between the various carriers and their methods for calculating allowable amounts found that most carriers adhered to the mandated formulae. There was usually consensus between the carriers when few drug products occupied a particular HCPCS code. This is the case of brand or trade name products, controlled by a single source.
>
> Confusion between the carriers increased as multiple source drugs appeared under the HCPCS Code (Table 5). Higher rates of disagreement for reimbursable amounts also appeared as larger numbers of RedBook prices became available.

(*Id.* at HHD128-0178.)

United States' Response: The United States does not dispute that Abbott has correctly, but selectively, quoted excerpts from a report prepared by Jing Xing Technologies, Inc., however the entirety of the report is the best evidence of its content. The United States disputes that the report is admissible given that it contains hearsay.

147. For claims processed during time periods where Dr. Duggan believed he has the array in effect for a particular J-Code, Dr. Duggan determined a "difference" for those claims through a methodology generally described on page 82 of his June 19, 2008 report:

> The goal of my analysis in this section is to determine the amount by which spending by the Medicare program on DME claims would have changed if alternative prices had been used for Abbott products. The mechanism for such a price effect is straightforward. If, for example, Abbott had one product in a particular carrier's array for one of the HCPCS codes listed in the complaint, then the median price from that array could change with an alternative price.
>
> Suppose for example there are three prices of 8, 10, and 12 in an array for three different products. If the price of 10 were to decline then the median would be

> certain to fall. If the price of 12 were to decline by more than 2 then the median would also fall. If however the price of 8 were to fall there would be no decline in the median. Thus to the extent that Abbott prices included in carriers' arrays tend to equal or exceed the median, it is more likely that the amount paid by Medicare would be affected by the use of alternative AWPs.

(Ex. DT, Duggan Rpt. at 82; *see also Id.* at 97-98.)

United States' Response: The United States does not dispute the above statement. The United States does not dispute that Abbott has correctly, but selectively, quoted excerpts from a report prepared by Dr. Duggan, however, the entirety of the report is the best evidence of its content.

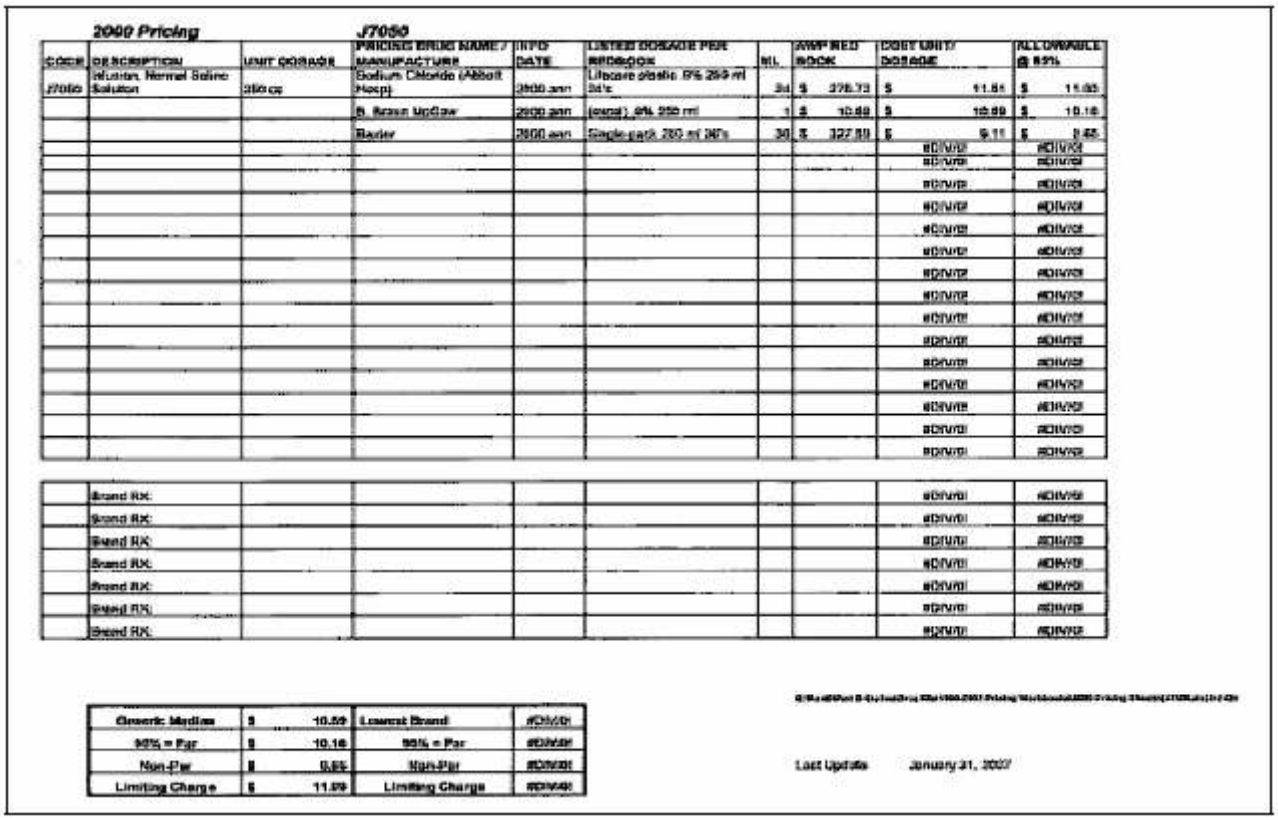
148. Dr. Duggan relied upon Myers and Stauffer to recreate those pricing arrays provided by the DOJ into Microsoft Excel spreadsheets. (Ex. DT, Duggan Rpt. at 85; Ex. DU, M. Duggan Dep. at 114:22-115:8.) He also relied upon Myers and Stauffer to recalculate the contractors' median AWP calculations by substituting in the applicable Dr. Duggan revised AWPs into the pricing array. (*E.g.*, Ex. DT, Duggan Rpt. at 97-101.) Then, using Medicare claims data provided by CMS and a computer algorithm, Dr. Duggan re-adjudicated all claims processed for the J-Code-quarters for which he determined he had pricing arrays in effect for those claims. (*E.g.*, *Id.* at 84-86.)

United States' Response: The United States does not dispute the above statement. The United States does not dispute that Abbott has correctly, but selectively, quoted excerpts from a report prepared by Dr. Duggan, however, the entirety of the report is the best evidence of its content.

149. Anytime there was a difference between what a contractor paid on a claim and what it allegedly would have paid had Dr. Duggan's revised arrays been used, Dr. Duggan computed a "difference" on that claim. (*Id.*) Thus, Dr. Duggan calculated a "difference" for claims reimbursed on the basis of a provider U&C charge. (*E.g.*, *Id.* at 98: "Thus for claims that paid the provider charged amount (as opposed to the calculated amount using the median above, from the third quarter of 2000 through and including the second quarter of 2001 (when $10.16 was the most common allowed amount), I determine whether Medicare spending would have fallen if the per-package price had been $8.65.").)

United States' Response: Undisputed.

150. Connecticut General produced an array for J7050, effective for the third quarter of 2000, depicted below:



2000 Pricing J7050

CODE	DESCRIPTION	UNIT DOSAGE	PRICING DRUG NAME / MANUFACTURER	INFO DATE	LISTED DOSAGE PER PRICING	ML	AWP PER BOOK	COST UNIT / DOSAGE	ALLOWABLE @ 83%
J7050	Infusion, Normal Saline Solution	250cc	Sodium Chloride (Abbott Hosp)	3Q00 ann	Lifecare plastic 0% 250 ml	24	$ 276.73	$ 11.54	$ 11.05
			B. Braun McGaw	2Q00 ann	(cena) 0% 250 ml	1	$ 10.69	$ 10.69	$ 10.16
			Baxter	2Q00 ann	Single-pack 250 ml 24's	24	$ 327.59	$ 9.11	$ 8.65
								#DIV/0!	#DIV/0!
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	Brand Rx:							#DIV/0!	#DIV/0!
	Brand Rx:							#DIV/0!	#DIV/0!
	Brand Rx:							#DIV/0!	#DIV/0!

Generic Median	$ 10.69	Lowest Brand	#DIV/0!
95% = Par	$ 10.16	95% = Par	#DIV/0!
Non-Par	$ 9.65	Non-Par	#DIV/0!
Limiting Charge	$ 11.59	Limiting Charge	#DIV/0!

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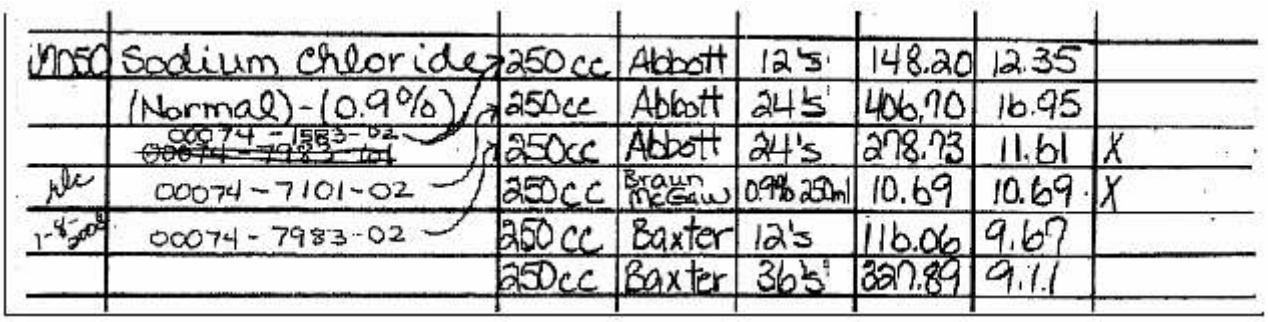
Ex. FB (AWQ005-0631).) Dr. Duggan's report contained a reproduction of this array and discussed of how substitution of his revised AWPs for Abbott NDCs would change the median AWPs computed from this array. (Ex. DT, Duggan Rpt. at 97.) Dr. Duggan's approach changed the median from $10.69 to $9.11, a decrease of 14.8%. (*Id.*)

United States' Response: The United States does not dispute the above statement, but clarifies that the reason the median changed was because Dr. Duggan replaced Abbott's inflated AWP of $11.61 that was used by Connecticut General in the array and replaced it with an Alternative AWP of $1.13 which was based on the actual average indirect pharmacy price scaled up by 25%. By omitting this additional information, Abbott fails to reveal that the spread on its product was approximately 1000%, in comparison to the conservative impact on damages of 14.8%. (Ex. DT, Duggan Rpt. at 97).

151. Wisconsin Physician Services ("WPS") produced an array for J7050, effective for the third quarter of 2000, depicted below:



J7050	Sodium Chloride	250 cc	Abbott	12's	148.20	12.35	
	(Normal) - (0.9%)	250cc	Abbott	24's	406.70	16.95	
	~~00074-1583-02~~ ~~00074-7983-02~~	250cc	Abbott	24's	278.73	11.61	X
Abc	00074-7101-02	250cc	Braun McGaw	0.9% 250ml	10.69	10.69	X
1-1-2000	00074-7983-02	250 cc	Baxter	12's	116.06	9.67	
		250cc	Baxter	36's	337.89	9.11	

(Ex. FC (AWQ036-0322).) Dr. Duggan's report contained a reproduction of this array and discussed how substitution of his revised AWPs for Abbott NDCs would change the median AWPs computed from this array. (Ex. DT, Duggan Rpt. at 104-05.) Dr. Duggan's approach changed the median from $11.15 to $5.82, a decrease of 47.9%. (*Id.*)

United States' Response: The United States does not dispute the above statement, but clarifies that the reason the median changed was because Dr. Duggan replaced Abbott's inflated AWPs of $12.35, $16.95 and $12.35 that were used by WPS in the array and replaced them with Alternative AWPs of $1.44, $2.33 and $3.02, respectively, which were based on the actual average indirect pharmacy prices scaled up by 25%. By omitting this additional information, Abbott fails to reveal that the spreads on its products were approximately 300% to almost 800%, in comparison to the conservative impact on damages of 47.9%. (Ex. DT, Duggan Rpt. at 97).

152. Often the Medicare contractors that did produce arrays were not able to produce arrays for all applicable quarters. (*E.g.*, Ex. DT, Duggan Rpt. at 101,107, 110, 118, 122.) Using a methodology generally described on pages 101-04 of his June 19, 2008 report, Dr. Duggan calculated a "difference" attributable to claims processed by certain of those contractors for certain of the quarters during the 1991 to 2001 damage period. In summary, Dr. Duggan analyzed the Medicare claims data produced by CMS to investigate whether Abbott NDCs were being used in the arrays during this earlier period. (*Id.* at 101.) He located those instances where claims were paid at levels matching an Abbott NDC AWP (or 90% or 95% of the AWP), from which he determined that an Abbott NDC was the median in those instances. He then determined whether the magnitude of these matches was prevalent enough to indicate that a carrier "was using Abbott NDCs in its arrays" for particular time periods. (*Id.* at 102.) If so, Dr. Duggan then aggregated all of the claims processed by that contractor for that particular time period and multiplied that figure by the

"ratio of DIFFERENCE" he computed for those time periods from that contractor where he did have arrays. (*E.g.*, *Id.* at 103: "I do the same for the total value of DIFFERENCE, though in this case I multiply the amount paid for J-Code during the 1995Q2 to 1996Q4 period by the ratio of DIFFERENCE to the total amount paid during the five subsequent years.").

United States' Response: The United States does not dispute that the above statement describes a portion of the analysis performed by Dr. Duggan. The entirety of Dr. Duggan's report is the best evidence of its content.

153. Table 43 of Dr. Duggan's June 19, 2008 report provided the "difference" figures that he computed for those Part B Carriers that produced pricing arrays. Dr. Duggan's Table 43 separately listed the "differences" attributable to extrapolated time periods. For example, Table 43 shows that $1,765,240 of the $2,547,863 "difference" calculated for Florida Blue Shield resulted from extrapolation.

United States' Response: The United States does not dispute the above statement describes a portion of the analysis performed by Dr. Duggan. The entirety of Dr. Duggan's report is the best evidence of its content.

154. Dr. Duggan also computed a "difference" attributable to Medicare claims processed by Part B Carriers that either did not produce arrays or were not included in those arrays that Dr. Duggan considered in his analysis. These "difference" figures are provided in Table 44 of Dr. Duggan's June 19, 2008 report. The methodology that Dr. Duggan used to compute these "differences" is described on pages 123-26 of his June 19, 2008 report. In summary, Dr. Duggan first constructed a composite "ratio of DIFFERENCE" by J-Code quarter from his analysis of the Part B Carriers that did produce arrays. (Ex. DT, Duggan Rpt. at 123.) Dr. Duggan then reviewed the Medicare claims data produced by CMS to evaluate the percentage of time that Carrier allowables for the five J-Codes equaled the published AWP price for an Abbott NDC (or 90% or 95% of that price). (*Id.* at 124.) On an aggregate, across J-Code basis, Dr. Duggan concluded that approximately 24% of the Medicare claims processed by those Carriers that did produce pricing arrays were traceable to an AWP for an Abbott NDC, versus approximately 18% for those Carriers that did not produce arrays. (*Id.*) Then, Dr. Duggan calculated a "difference" for claims processed by Carriers which did not produce arrays by extrapolating his composite "ratio of DIFFERENCE," or "DIFF-FRAC," calculated from Carriers which produced arrays. (*Id.* at 125.) Dr. Duggan scaled down this calculation to take account of his finding that Carriers not producing arrays were less likely than Carriers which did produce arrays to have an allowable matching an Abbott NDC. (*Id.*)

United States' Response: The United States does not dispute the above statement

describes a portion of the analysis performed by Dr. Duggan. The entirety of Dr. Duggan's report is the best evidence of its content.

155. Myers and Stauffer recreated five applicable arrays for J7050 from Part B Carrier Cigna. (Ex. FD (Myers and Stauffer recreated arrays).) The following table indicates the NDCs that were included in the five arrays for J7050 produced by Cigna.

	1997	1999 Q2	2000 Q2	2000 Q3	2001 Q3
Abbott	74-7101-02: **$13.93**				74-7101-02:**$16.95**
	74-1583-02: **$10.15**	74-1583-02: **$11.75**			74-1583-02: **$12.35**
	74-7983-02: **$9.56**		74-7983-02: **$11.61**	74-7983-02: **$11.61**	74-7983-02: $**11.61**
	74-6138-02: **$12.14**				
					74-7985-02: **$12:35**
					74-7132-02: **$16.95**
Baxter	NDC not identified: **$4.96**				
	NDC not identified: **$9.67**				00338-0049-02: **$9.67**
	NDC not identified: **$11.56**				
	NDC not identified: **$9.11**	NDC not identified: **$9.10**	00338-0049-02: **$9.11**	NDC not identified: **$9.11**	00338-0049-02: **$9.11**
McGaw	NDC not identified: **$10.26**				
		NDC not identified: **$12.30**			
			00264-7800-02: **$10.69**	NDC not identified **$10.69**	00264-7800-02: **$10.69**

(*Id.*)

United States' Response: The United States does not dispute the above statement, however, the entirety of the arrays prepared by Myers and Stauffer is the best evidence of their content.

156. For four of the five J-Codes at issue, Florida Blue Shield produced arrays for just two quarters (Q1 and Q2 1997). The Florida Blue Shield 30(b)(6) witness provided the following testimony regarding its practices in creating pricing arrays:

> Q. Sure. If a particular manufacturer had more than one product for a particular J-Code and it was the same dosage amount as what was being arrayed–
>
> A. Uh-huh.
>
> Q. -would First Coast include both of those product listings in the array?
>
> A. I didn't, but I'm not sure if anyone else had ever done that in the past.
>
> Q. Why did you not do so?
>
> A. I just didn't have any instructions to do so, so I didn't think you should do it. I figured one was enough.
>
> * * *
>
> Q. Now, consistent with the practice that you testified earlier to only include one product from each manufacturer, is that why Abbott's second product was not included in this pricing array?
>
> A. Yes.
>
> Q. And would you expect this to be the same methodology applied for the time period of 1991 through 2001?
>
> A. I would expect it, but I can't really be sure.
>
> Q. That's because we don't have the-
>
> A. Right.
>
> Q. -actual pricing arrays; is that correct?
>
> A. That's correct.
>
> MR. LAVINE: Object to form.

(Ex. FE, 30(b)(6) Dep. of First Coast Service (successor to Florida Blue Shield at 82:21-83:11, 101:20-102:17.)

United States' Response: The United States does not dispute that Abbott has accurately, but selectively, quoted portions of the deposition of First Coast Service. The entire transcript is

the best evidence of its contents. The United States disputes that it would have a material effect on Dr. Duggan's calculations.

F. Examples of Evidence That Duggan Did Not Consider

157. Apart from tasking Myers and Stauffer to review the deposition testimony taken of state Medicaid officials as it might relate to the states' adjudication formulas, Dr. Duggan did not consider the testimony of state Medicaid officials in calculating his "difference" figures. Dr. Duggan gave the following testimony:

> Q. You understand that since we last met in July of 2008, a number of state Medicaid programs have-have provided deposition testimony, right?
>
> A. That is my understanding.
>
> Q. A lot of people who actually worked in these programs during the relevant time period have been deposed and provided extensive testimony, right?
>
> MR. LAVINE: Object to form.
>
> THE WITNESS: I-I haven't examined when the various folks worked. This 2001 is the end of the period, so that was eight years ago. But I understand that there has been some deposition testimony by officials from multiple states so I'm aware of that.
>
> BY MR. TORBORG: Q. What have you done to review that testimony?
>
> A. At my direction, Myers and Stauffer is-has considered those-those depositions as they strive to arrive at the most accurate description possible of state Medicaid adjudication algorithms.
>
> Q. So your understanding is that you've instructed Myers and Stauffer to review these depositions for purposes of what they may provide in terms of the adjudication formulas, right?
>
> A. I have instructed them to-yes. That's correct.
>
> Q. Have you reviewed yourself any of the testimony that has been taken since your last deposition of a state Medicaid official?
>
> A. Not that I recall.
>
> Q. And apart from some of the transcripts that I-some excerpts that I showed you of testimony last time, have you reviewed any other Medicaid testimony that was taken before July of 2008 in these cases or any other case?
>
> MS. THOMAS: Objection. Form.

THE WITNESS: I don't recall myself reading such transcripts, but I certainly have instructed Myers and Stauffer to study and examine this information in addition to other information.

(Ex. DU, M. Duggan Dep. at 678:16-690:14.)

United States' Response: The United States disputes the above statement to the extent that it asserts that Dr. Duggan did not consider material information about the specific state Medicaid programs' reimbursement methodologies in his calculations, including through his use of the Myers and Stauffer summaries. The United States does not dispute that Abbott has accurately, but selectively, quoted portions of the deposition of Dr. Duggan. The entire transcript is the best evidence of its contents.

158. Dr. Duggan did not analyze what state Medicaid or CMS officials understood about the relationship between marketplace prices and reported prices for the products at issue in this case. Dr. Duggan provided the following testimony:

Q. You have not done a review in your work here regarding what state Medicaid programs, Congress or CMS knew about the relationship between marketplace prices and reported prices for the drugs at issue in this case; is that right?

MR. LAVINE: Object to form.

A. That wasn't the main focus of my analysis. But I have certainly seen some written material indicating that there may have been some awareness of this issue of a deviation between actual prices paid in the marketplace and those published in the Red Book and in First Databank and so forth. But I'm-so I've seen some discussion of that issue, but that-so I'm aware of it. But that really hasn't been-as you can see from the sort of overview of my report, that's really not the focus of my report.

(Ex. DU, M. Duggan Dep. at 282:16-283:9.)

Q. And I take it that you're not familiar with the extensive testimony that's been provided by state Medicaid witnesses about how they knew of larger spreads for generic drugs than brand name drugs throughout the entirety of the time period of your analysis, correct, because you haven't reviewed the testimony, right?

MR. LAVINE: Object to form.

THE WITNESS: That wasn't the focus of my analysis. We discussed, for example, some documents last time where-in which larger disparities were

> discussed for generic versus brand drugs, whether they were in the neighborhood of kind of spreads that were in this case, it-I'm not sure, but in any case, it was not the focus of my analysis to-that was not the focus of my analysis, what the state Medicaid officials knew.
>
> Q. Did you know that state Medicaid officials sat around in a meeting in Richmond in 1994, where they talked about the fact that hospitals and home infusion pharmacies could purchase drugs at even greater discounts than other pharmacies?
>
> MR. LAVINE: Object to form.
>
> THE WITNESS: I'm not aware of that me(et)ing.

(*Id.* at 850:16-851:21; see also Ex. DX, M. Duggan Rebuttal Dep. (5/19/09) at 294:1-16; 342:20-344:5; 358:7-14.)

United States' Response: The United States disputes the above statement to the extent that it asserts that Dr. Duggan did not consider material information about the specific state Medicaid programs' reimbursement methodologies in his calculations, including through his use of the Myers and Stauffer Summaries. The United States does not dispute that Abbott has accurately, but selectively, quoted portions of the deposition of Dr. Duggan. The entire transcript is the best evidence of its contents.

159. Dr. Duggan's "difference" calculations assumed that state Medicaid programs and Medicare actually would have used the lower revised prices he utilizes in his "difference" calculation. Dr. Duggan provided the following testimony:

> Q. Are you providing expert opinion in this case on whether the state Medicaid programs or Medicare would have used the alternative prices that you calculate in your report?
>
> MR. LAVINE: Objection to form.
>
> A. It is my understanding-and I try to be specific about this in my report. It is my understanding that-it is my assumption that if Abbott had reported alternative prices to First Databank as I described in my report and to the Red Book that state Medicaid agencies and Medicare insurance carriers would have used those prices when adjudicating Medicaid and Medicare claims. That is a sort of-that is an assumption that I am making in my report. And I try to be clear about that.

(Ex. DU, M. Duggan Dep. at 215:2-16.) Dr. Duggan did not analyze the reaction of state Medicaid programs or Medicare to revised pricing information provided by the DOJ for

Abbott's vancomycin, dextrose, or sterile water. (*Id.* at 865:10-868:6.)

United States' Response: The United States disputes the above statement to the extent that it asserts that Dr. Duggan did not consider material information about the specific state Medicaid programs' reimbursement methodologies in his calculations, including through his use of the Myers and Stauffer summaries. The United States does not dispute that the Defendant has accurately, but selectively, quoted portions of the deposition of Dr. Duggan. The entire transcript is the best evidence of its contents.

160. Dr. Duggan did not consider reports prepared by Myers and Stauffer for state Medicaid programs on the cost to dispense prescriptions, including for intravenous prescriptions, or studies prepared by Myers and Stauffer on the acquisition costs of drugs. (Ex. DU, M. Duggan Dep. at 361:20-364:2.) Myers and Stauffer did not make Dr. Duggan aware of prior studies done by Myers and Stauffer showing a higher cost to dispense associated with dispensing intraveneous prescriptions. (*Id.* at 365:1-7.) Dr. Duggan did not believe such information is "necessary for the analysis that (he) carried out in (his) report." (*Id.* at 370:3-8.)

United States' Response: The United States disputes the above statement to the extent that it asserts that Dr. Duggan did not consider material information about the specific state Medicaid programs' reimbursement methodologies in his calculations, including the dispensing fees applicable to the claims he considered, or based upon his use of the Myers and Stauffer summaries.

161. Prior to serving his first report in this case, Dr. Duggan did not consider the following testimony provided by CMS's Deidre Duzor, the co-leader of the CMS pharmacy team:

> Q. If, tomorrow, the AWPs published in Redbook were-instead of as they are today were, instead, empirical averages of the amounts that pharmacies and providers paid for drugs-do you understand the premise of my question there?
>
> A. I think so.
>
> Q. Do you have any opinion about whether there would be access problems for beneficiaries of Medicaid if that were to happen overnight?
>
> MS. MARTINEZ: Objection. Form.

THE WITNESS: I will restate your question; you can tell me if it's accurate. If Medicaid was paying pharmacies at a rate lower than what their purchase price of the drug is-

BY MR. COOK: Yes, ma'am.

A. -would there be access problems?

Q. Yes.

A. I would guess there would be.

Q. Why?

A. Why?

Q. Yes, ma'am.

A. Because pharmacies would stop serving Medicaid in order to try to get the reimbursement to be raised.

Q. Do you have any opinion about what would be the consequence if the various state Medicaid programs were paying based upon an AWP that was an empirical average of what pharmacies were obtaining drugs for?

A. Well, states don't want to cause access problems any more than the federal government does, so if the new AWPs would turn out to be actual purchasing-the price at which the drug could be purchased, I think states-we would have a run on state plan amendments to change their formula for reimbursement.

(Ex. FF, D. Duzor Dep. at 904:6-905:21; *see also* Ex. DU, M. Duggan Dep. at 271:22-274:22.)

United States' Response: The United States does not dispute the above statement to the extent that it merely states that Dr. Duggan did not read this particular testimony. The United States disputes any assertion or implication that Dr. Duggan failed to consider material information about the specific state Medicaid programs' reimbursement methodologies in his calculations, including by virtue of his use of the Myers and Stauffer summaries. The United States does not dispute that the defendant has accurately, but selectively, quoted portions of the deposition. The entire transcript is the best evidence of its contents.

162. Prior to serving his first report in this case, Dr. Duggan did not consider the following testimony from Minnesota Medicaid Pharmacy Director Cody Wiberg:

> A. . . . We know AWP, "ain't what's paid." But if we move towards more transparency and we get closer to reimbursing on the ingredient side at what providers actually pay, then we have to look at the dispensing fee side in the case of pharmacies, because we've always kept that below what we think the true cost of dispensing is to make up for the fact that there is some money being made on the ingredient side. So to the extent, again, that you start paying people a dispensing fee or a total reimbursement that does not even get back the cost of the drugs, plus the cost of labor and the computer systems and the lights and all that, you could have providers stop-you know, start dropping out of Medicaid. And then this creates an access issue for very poor people.

(Ex. AH, C. Wiberg Dep. 172:3-18; *see also* Ex. DU, M. Duggan Dep. at 307:16-310:4.)

United States' Response: The United States does not dispute the above statement to the extent that it merely states that Dr. Duggan did not read this particular testimony, however, to the extent that it asserts or implies that Dr. Duggan did not consider material information about the specific state Medicaid programs' reimbursement methodologies in his calculations, the United States disputes the above statement.

163. Prior to serving his first report in this case, Dr. Duggan did not consider the following testimony of Missouri pharmacist consultant Susan McCann:

> Q. . . . But is it your belief and your understanding as the pharmacist working at Missouri Medicaid that Missouri Medicaid knew it was paying a higher ingredient cost reimbursement than acquisition cost in order to compensate for a dispensing fee that was lower than what it otherwise thought it should have been?
>
> (Objection)
>
> A. That was my understanding.

(Ex. AG, S. McCann Dep. at 479:6-16; *see also* Ex. DU, M. Duggan Dep. at 319:9-320:11.)

United States' Response: The United States does not dispute the above statement to the extent that it merely states that Dr. Duggan did not read this particular testimony, but to the extent that the above statement asserts or implies that Dr. Duggan did not consider material information about the specific state Medicaid programs' reimbursement methodologies in his calculations, the United States disputes the above statement. The United States does not dispute that the defendant

has accurately, but selectively, quoted portions of the deposition. The entire transcript is the best evidence of its contents.

164. Prior to serving his first report in this case, Dr. Duggan did not consider the following testimony of former Tennessee pharmacy director Leo Sullivan:

> Q. And do you know in Tennessee, either before TennCare or after TennCare was paying a compounding fee for IV? Do you know if that was something that was being paid?
>
> A. Ah, no. But there's, there's ways to pay it without, without having a separate-you know, I noticed on here that one form is for payment, one form is for reimbursement of supplies, one form is for-you know, they're, they're making a variety to submit multiple forms. And I wouldn't-I can't tell you a specific product or specific time period, but one of my strategies was in issues like this, where compounding was involved, I didn't want to go down the road, at least in the early Nineties, of getting into paying for compounded prescriptions, because that can-that could range from a sterile product all the way down to an ointment, okay? And, and our claims reimbursement system hadn't evolved to the current NCPDP sophistication of today. So it was very hard to put in a, a set compounding fee for what, what products? One may take a minute to make, one may take an hour and a half. So getting back to, to the MAC issue, some, sometimes for certain products in this arena, you would take that into account for the MAC. For example, I might say, I'm not paying for the tape that you use to hold the IV needle into place. I'm not paying for the IV needle or the tube set. I'm not going to-I don't want bills for that. I know you've got to do it to administer this drug. So we're going to add on the cost of this drug X, because I know this, this and this always goes with it, and I know there is a fixed cost for that, but I don't want five bills. I want 10 different places. Bill me for the drug. And I'll make sure that the-whatever the MAC is incorporates all your other costs. And you have to talk with providers and know what that is. I mean, you know.
>
> Q. So, in short, you would use the payment for the drug itself to cross-subsidize other things that might need to be paid to fairly-
>
> A. And that would include compounding.
>
> Q. And it may include nursing services that were not included, things of that nature?
>
> A. (Nodding yes.)

(Ex. AJ, L. Sullivan Dep. at 152:16-154:22; *see also* Ex. DU, M. Duggan Dep. at 599:21-607:6.) In response to this testimony, Dr. Duggan stated:

> Q. And there may be states all across the 50 states that incorporated the same kind of thinking and logic as Mr. Sullivan testified that he used for Tennessee,

right? You don't know because you haven't talked to all those people, right?

MR. LAVINE: Object to form.

A. It's difficult for me to speculate what people in other states are thinking or have in mind or what the policymakers in those other states have in mind. That wasn't the focus of my analysis.

(*Id.* at 606:19-607:6.)

United States' Response: The United States does not dispute the above statement to the extent that it merely states that Dr. Duggan did not read this particular testimony, however, the United States disputes the statement it to the extent that it asserts or implies that Dr. Duggan did not consider material information about the specific state Medicaid programs' reimbursement methodologies in his calculations. The United States does not dispute that the defendant has accurately, but selectively, quoted portions of the deposition. The entire transcript is the best evidence of its contents.

165. On May 3, 2008, the DOJ sent Myers and Stauffer's Keenan Buoy a letter attaching "certain laws of the State of New York government pharmacy reimbursement for drugs under New York's Medicaid program." (Ex. FG (Abbott Duggan Ex. 10).) The Addendum to the DOJ's letter set forth the relevant text of certain statutory amendments enacted by the state of New York. (*Id.*) DOJ's letter concluded by stating: "Feel free to share this letter with Professor Mark Duggan should you deem it appropriate. If you do, please let me know." (*Id.*) Included in the text of statutory amendments enacted by the state of New York is the following language from the 217th Legislature, approved June 9, 1994:

§ 564. This act shall take effect immediately provided, however, that:

* * *

the provisions of section four hundred fifty-six of this act, amending section 367-a of the social services law in relation to the payment of a dispensing fee for certain drugs dispensed by pharmacies under the medical assistance program shall be effective if, and for so long as, the provisions of this act in relation to payment for ingredient costs for multiple source prescription drugs and brand-name prescription drugs for which no specific upper limit has been set by the federal health care financing agency as implemented by the department of social services are not found by any court or federal administrative body to be in violation of current federal law or regulation relating to the levels of payment for prescription drugs under the federal medicaid program pursuant to

title XIX of the federal social security act; *provided further, however, that if any court or federal administrative body finds that the provisions relating to the ingredient costs for multiple source prescription drugs and brand-name prescription drugs for which no specific upper limit has been set by the federal health care financing agency as implemented by the department of social services are found to be in violation of current federal law or regulation relating to the levels of payment for prescription drugs under the federal medicaid program pursuant to title XIX of the federal social security act, the department of social services shall establish a formula for paying pharmacies for such drugs in a manner consistent with current federal law and regulation and a dispensing fee which shall reflect appropriate adjustments so that the established formula is implemented in a fiscally neutral manner . . . .*

(Ex. FG at EXP USABT-DUG 145749-50) (emphasis added). When asked if he considered this language, Dr. Duggan provided the following testimony:

> Q. So it appears at least based on your lack of recollection of the document today that Myers and Stauffer did not deem it appropriate to share this letter with you?
>
> MR. GOBENA: Objection to the form.
>
> Q. Or this-not letter. Statute.
>
> MR. GOBENA: Same objection.
>
> A. I hesitate to say that they did not. I have received quite a few e-mails and documents and I've seen plenty of documents that look like this. But this one, it just doesn't leap to mind right now.
>
> * * *
>
> Q. In any event, you didn't consider this regulation in forming your difference calculation, correct?
>
> A. It is possible that I considered-received this document and considered it. As I said earlier, it's difficult to disentangle the impact of any specific piece of information on my ultimate analyses. I don't recall it here sitting in front of you. But we've talked a bit about this dispensing fee-the set of issues surrounding dispensing fees.
>
> Q. Okay.
>
> A. And so I don't know all that underlies this in New York in 1994.

(Ex. DX, M. Duggan Rebuttal Dep. at 415:4-15, 418:8-21.)

United States' Response: The United States does not dispute the above statement to the extent that it merely states that Dr. Duggan did not personally see the document referenced,

however, the United States disputes the above statement to the extent that it asserts or implies that Dr. Duggan did not consider material information about the specific state Medicaid programs' reimbursement methodologies in his calculations. The United States does not dispute that the defendant has accurately, but selectively, quoted portions of the deposition. The entire transcript is the best evidence of its contents.

166. Dr. Duggan did not analyze the adequacy of the Medicaid dispensing fees paid for the drugs at issue in this case, or the costs to dispense those products. (Ex. DU, M. Duggan Dep. at 346:9-14; Ex. DX, M. Duggan Rebuttal Dep. at 382:21-383:6.)

United States' Response: The United States disputes the above statement to the extent that it asserts that Dr. Duggan did not consider material information about the specific state Medicaid programs' reimbursement methodologies in his calculations. He considered the dispensing fees applicable to the claims that were the subject of his calculations.

VI. OTHER

167. On November 12, 2008, the United States informed counsel for the Defendants that "Plaintiffs have made the determination to drop our claim for the federal share of Medicaid damages for Medicaid claims in the state of Ohio for the subject drugs during the time period at issue . . . ." (Ex. FH (Nov. 12, 2008 Letter from B. Smith to D. Torborg, E. Gortner, and N. Merkl).)

United States' Response: The United States does not dispute that it informed counsel of the selectively quoted language in the document attached as Exhibit FH from AUSA Smith. The entirety of the document is the best evidence of its content. This statement of fact does not set forth any factual information material to this case. The United States further states that it is moving to dismiss its claims with respect to Ohio.

168. On November 19, 2008, Abbott requested that the Government explain " . . . why, after issuing a 30(b)(6) notice to Ohio, conducting years of investigation and formal discovery, and asserting (or having its expert calculate) damages for Ohio," it was no longer seeking to recover damages relating to the state of Ohio. (Ex. FI (Nov. 19, 2008 Letter from D. Torborg to B. Smith).) The United States did not respond to Abbott's November 19th

letter.

United States' Response: The United States does not dispute that Abbott requested the information contained in the quoted language in the document attached as Exhibit FI. The entirety of the document attached as FI is the best evidence of its content. However, this statement of fact does not set forth any factual information material to this case. Moreover, the United States is moving to dismiss that portion of its Amended Complaint that seeks damages for claims paid by the Ohio Medicaid program.

169. In its interrogatory response, the United States stated: "While Abbott profited from the fraudulent price reporting from at least 1991 through 2001, Medicare and Medicaid paid in excess of $69 million for Vancomycin alone and approximately $145 million for large volume parenterals referred to in the United States' Complaint." (Ex. DS at 42 (Abbott Ex. 333).) The United States also stated that "[t]he United States will rely on testifying experts to provide further damages calculations. The expert reports will be provided pursuant to Fed. R. Civ. P. 26 and the Court's scheduling order in this case." (*Id.* at 42-43.)

United States' Response: The United States does not dispute that Abbott requested the information contained in the selectively quoted language in its Answer to Abbott's Interrogatory No. 9. However, the United States' Response to Abbott's Interrogatory 9, as reflected in Exhibit DS, is much more detailed and involved than the portions selectively quoted in this statement of fact. Abbott's selective quotes herein must be read in the context of the entirety of the United States' Answer to Interrogatory No. 9.

170. On March 31, 2008, Abbott filed a motion to compel production of documents from the United States. (Dkt. No. 5173.) One of the topics for which Abbott sought production was "a representative sample of the allegedly false claims at issue in the case." (*Id.* at 1.)

United States' Response: The United States does not dispute the above statement, with the following qualification. Although the Government produced all of its claims data in this case, it was ordered to produce a sample as well. With respect to the format for the sample, the

Magistrate Judge directed defense counsel to "sit down and work it out what it is you would like on a sample basis." 12/4/2008 Hrg. Trans. at 52. After the hearing, Government counsel asked Abbott's attorney to provide specifications for the sample. Defense counsel advised that he would refer the question to other attorneys at his firm. Thereafter, the Government never heard from Abbott again on this issue. The Government sent Abbott a sample of data on December 18, 2008. Prior to the summary judgment motion, Abbott never challenged whether the Government's sample was sufficient or compliant via a motion pursuant to Fed. R. Civ. P. 37(b).

171. On December 4, 2008, the Court heard arguments pertaining to Abbott's motion to compel a representative sample of the allegedly false claims at issue in the case. (See *Id.*) The Court granted Abbott's motion to compel and ordered the Government to produce a representative sample of the allegedly false claims at issue in this case. (Ex. FJ at 51:22-23).)

United States' Response: The United States incorporates its response to Statement of Fact 170 above.

172. In 1997, Abbott made the decision to discontinue its Home Infusion Services component and spent the next four to five years completing the contracts which it had at that time. (Ex. FK, M. Sellers Dep. at 30:18-31:20; 66:19-67:3.)

United States' Response: The United States does not dispute the above statement, with the qualification that "discontinue" during those five years meant that Abbott did not take on new Home Infusion clients. It still honored and continued to perform services under its existing home infusion arrangements, and Abbott still operated one or more of its own pharmacies until 2001. Qualifying further, Abbott did not "discontinue" billing Medicare and Medicaid on its own behalf and on behalf of its Home Infusion revenue partners with current contracts until at least 2001. *See* (US-A-SF ¶¶ 142-143).

173. According to the reimbursement summaries prepared by Myers & Stauffer for this litigation, at least 9 states-Alabama, Florida, Illinois, Maryland, Massachusetts, Missouri,

Ohio, Rhode Island, and Texas-included WAC in their payment formula for some portion of the 1991 to 2001 time period. (Ex. AS, Myers and Stauffer Medicaid Pharmacy Reimbursement Methodology schedules.) For portions of this time period, four states defined EAC exclusively in terms of WAC-Alabama, Florida, Massachusetts, and Rhode Island. (Ex. FL (EXP USABT-DUG 068539-47) (Alabama); Ex. FM (HHC008-0029) (Florida); Ex. FN (EXP USABT-DUG 068804-21) (Florida); Ex. FO (EXP USABT-DUG 069122-30) (Massachusetts); Ex. FP (EX USABT-DUG 069586 - 600 (Rhode Island).)

United States' Response: The United States does not dispute the above statement, with the qualification that eleven states have used WAC during at least some of the period covered by the summary. An additional four states have used both AWP and WAC as the basis for determining EAC during the entire period of 1991 to the present. Henderson Decl. ¶ 24. As Abbott Exhibit AS reflects, many use a "lower of" methodology, and some use alternatives to WAC. Therefore, the United States disputes that it is appropriate to identify each state listed as "WAC" state. Additionally, Myers and Stauffer has produced and verified summaries for the States of Alabama, Florida, Illinois, Maryland, Massachusetts, Missouri, Ohio, Rhode Island, and Texas, which reflect, among other things, whether and to what degree each State relied upon WAC. (Henderson Decl. at Exhibit 24). Qualifying further, any facts pertaining to Ohio's use of WAC is immaterial, as the United States is moving to dismiss all Ohio claims. Qualifying further, Abbott Exhibits FL, FM, FN, PO and FP, in their entirety, are the best evidence of their content. However, the documents are excerpted, in some places unidentified, and are not documents that appear to bind the States of Alabama, Florida, Massachusetts and Rhode Island. Therefore, with respect to Abbott's factual assertion that "[f]or portions of this time period, four states defined EAC exclusively in terms of WAC-Alabama, Florida, Massachusetts, and Rhode Island. (Ex. FL (EXP USABT-DUG 068539-47) (Alabama); Ex. FM (HHC008-0029) (Florida); Ex. FN (EXP USABT-DUG 068804-21) (Florida); Ex. FO (EXP USABT-DUG 069122-30) (Massachusetts); Ex. FP (EX USABT-DUG 069586 - 600 (Rhode Island)", the purported record evidence provided

does not support the factual contention for which it is asserted, and this statement is therefore disputed.

174. Of the 44 Abbott NDCs at issue in this case, prior to April 2001, First DataBank reported WACs for only two-00074613803 (saline solution) and 00074613903 (sterile water irrigation)-during the January 1, 1991 to December 21, 2001 time period. First Databank reported WACs for 00074613803 and 00074613903 starting on April 29, 1996. (See CD HHD124, file names 94_prices_all, 95_prices_all, 96_prices_all, 97_prices_all, 98_prices_all, 99_prices_all, 00_prices_all, 01_prices_all) (CDs are not included with this filing).

United States' Response: The United States does not dispute that the only WACs that appear in the First Databank database for the Subject Drugs are for NDC numbers 00074613803 and 00074613903.

Respectfully Submitted,
For the United States of America,

MICHAEL K. LOUCKS
ACTING UNITED STATES ATTORNEY

/s/ George B. Henderson, II
George B. Henderson, II
Assistant U.S. Attorney
John Joseph Moakley U.S. Courthouse
Suite 9200, 1 Courthouse Way
Boston, MA 02210
Phone: (617) 748-3272
Fax: (617) 748-3971

JEFFREY H. SLOMAN
ACTING UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF FLORIDA

/s/ Mark A. Lavine
Mark A. Lavine
Ann St.Peter-Griffith
Special Attorneys for the Attorney General
99 N.E. 4th Street, 3rd Floor
Miami, FL 33132
Phone: (305) 961-9003
Fax: (305) 536-4101

MICHAEL F. HERTZ
DEPUTY ASSISTANT ATTORNEY GENERAL

/s/ Renée Brooker
Joyce R. Branda
Daniel R. Anderson
Renée Brooker
Justin Draycott
Rebecca A. Ford
Gejaa T. Gobena
Elizabeth Strawn
Civil Division
Commercial Litigation Branch
P. O. Box 261
Ben Franklin Station
Washington, D.C. 20044
Phone: (202) 307-1088
Fax: (202) 307-3852

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